Common Market for Eastern and Southern Africa

Gap Assessment of Laboratory Systems in Selected COMESA Member States

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Table of Contents

[**ACRONYMES AND ABBREVIATIONS** 2](#_Toc8493697)

[**OBJECTIVE OF THE ASIGNMENT** 7](#_Toc8493698)

[**MAIN ACTIVITIES** 7](#_Toc8493699)

[**RESULTS** 7](#_Toc8493700)

[**ETHIOPIA** 7](#_Toc8493701)

[**KENYA** 19](#_Toc8493702)

[**MADAGASCAR** 37](#_Toc8493703)

[**MAURITIUS** 42](#_Toc8493704)

[**RWANDA** 48](#_Toc8493705)

[**UGANDA** 55](#_Toc8493706)

[**ZAMBIA** 68](#_Toc8493707)

[**CONCLUSIONS** 79](#_Toc8493708)

[**RECOMMEDATIONS** 80](#_Toc8493709)

[**ANNEXES** 81](#_Toc8493710)

# **ACRONYMES AND ABBREVIATIONS**

#

AGOA: African growth and opportunity Act

AOAC: Organization of Official Analytical Chemists

APHA: American Public Health Association

APQMTL : **A**gricultural Product Quality Monitoring and Testing Laboratory

ASTA: American Spice Trade Association

ASTM: American Society for Testing and Materials

AWWA: American Water Works Association (AWWA

BIPEA: Bureau InterProfessionnel d'Etudes Analytiques

CAB: Conformity Assessment Body

CEN: European Committee for Standardization

CCP: Critical Control Point

CNRE: Centre National de Recherches sur l’Environnement

COMESA: Common market for Eastern and Southern Africa

DAkkS: Deutsche Akkreditierungsstelle

EAC: East African Community

ECAE: Ethiopian conformity assessment enterprise

ECD: Electron Capture Detector

EU: European Union

FAPAS: Food Analysis Performance Assessment Scheme

FBO: Food Business Operator

FDA: Food and Drug Administration

FSMA: Food Safety Modernization Act

GC: Gas Chromatograph

HACCP: Hazard Analysis Critical Control Points

HMF: Hydroxymethylfurfural

HPLC: High Performance Liquid Chromatograph

IAEA: International Atomic Energy Agency

ICP-OES: Inductively coupled plasma - optical emission spectrometer

ISO: International organization for Standardization

KEBS: Kenya Bureau of Standards

KEPHIS: Kenya Plant Health Inspectorate Service

LACAE: Laboratoire d’Analyse et de Contrôle des Aliments et des Eaux

NMISA: National Metrology Institute of South Africa,

MS: Mass Spectrometer

NABL: National Accreditation Board for Testing and Calibration Laboratories

NPD: Nitrogen Phosphorous Detector

NFSCC: National Food Safety Committee

PAHs: Polycyclic aromatic hydrocarbons

PT: Proficiency Testing

QUATEST: Quality Assurance & Testing Centre

QMS: Quality Management System

SANAS: South African National Accreditation System

SADCMET: Southern African Development Community Cooperation in Measurement Traceability

SOP: Standard Operating Procedure

SANAS: South African National Accreditation Service

SPS: Sanitary and Phytosanitary

TMEA: Trade Mark East Africa

US: United States

USDA: United States Department of Agriculture

XRF:X-ray fluorescence

**INTRODUCTION**

The United States (US) through the African Growth and Opportunity Act (AGOA) is a major trading partner with COMESA member states. According to a draft Baseline Review of Food Exports from Selected COMESA countries to the US in 2017, agricultural products including coffee, tea & spices constituted the third top import category, $744 million worth after fuels ($1.6 billion) and woven apparel ($789 million). Apart from coffee, tea & spices there are other export agricultural products, and all must conform to the US market.

In the US, nutrition information is required on packaged retail foods in the form of food labelling, to comply with Food and Drug Administration (FDA) labelling regulations. The "Nutrition Facts" on the label must show total fat, saturated fat, cholesterol, sodium, total carbohydrate, fibre, sugar, protein, vitamin A, vitamin C, calcium and iron content. In addition, it may include nutrition claims such as "low fat", "low cholesterol" and “low sugar.” Consumers can use this information to select healthy foods and make informed buying decisions. This allows manufacturers to be competitive and develop new products, increasing consumer choice. The FDA sets action levels that specify maximum levels of specific contaminants that may be found in a food sample.

The above requirements dictate that food manufacturers or Food Business Operators (FBOs) put traceability systems in place to ensure their food products are safe, with no contaminants or harmful residues, and to provide accurate nutritional information. General laboratory testing required on food products include the following:

* Chemical testing for identification and quantification of contaminants e.g. heavy metals and pesticides, chemical components e.g. pH, additives and preservatives among others.
* Microbiology testing for spoilage organisms and pathogens
* Food nutrition analysis to provide information for nutrition labelling on food packaging that manufacturers are required to include to comply with the labelling regulations of destination countries.
* Food allergen testing

Testing laboratories facilitate the monitoring of critical Control Points (CCPs) in Hazard Analysis Critical Control Points (HACCP) certified enterprises. They are part of the domestic quality infrastructure which includes other Conformity Assessment Bodies (CABs) involved in inspection and certification. This infrastructure is required for the effective operation of domestic trade, and their international recognition is important to enable access to foreign markets. Accredited CABs in the countries of origin enables them to offer their services to local clients at competitive prices thus, resulting in reduced production costs for local manufactures/FBOs and reducing delays at the borders of importing countries.

The US-FDA Food Safety Modernization Act (FSMA) was signed into law in January 2011. Section 422, “LABORATORY ACCREDITATION FOR ANALYSES OF FOODS” under TITLE II—"IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS”, requires the secretary, United States Department of Agriculture (USDA) to establish:

1. a program for the testing of food by accredited laboratories;
2. a publicly available registry of accreditation bodies recognized by the Secretary and laboratories accredited by a recognized accreditation body

The program under ‘a’ shall provide for the recognition of laboratory accreditation bodies that meet criteria, established by the Secretary for accreditation of laboratories, including independent private laboratories, with a demonstrated capability to conduct 1 or more sampling and analytical testing methodologies for food.

The Secretary shall develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body for a specified sampling or analytical testing methodology. The model standards shall include:

(A) methods to ensure that:

1. appropriate sampling, analytical procedures (including rapid analytical procedures), and commercially available techniques are followed, and reports of analyses are certified as true and accurate;
2. internal quality systems are established and maintained
3. procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is accredited; and
4. individuals who conduct the sampling and analyses are qualified by training and experience to do so; and

(B) any other criteria determined appropriate by the Secretary.

The Secretary may waive requirements under this subsection if—

1. a new methodology or methodologies have been developed and validated but a laboratory has not yet been accredited to perform such methodology or methodologies and
2. the use of such methodology or methodologies are necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

Thus, for a laboratory to be considered for recognition under the FSMA, it must be accredited by a recognised body and must validate all the applicable testing methods.

# **OBJECTIVE OF THE ASIGNMENT**

The objective of the assignment was to assess the status of selected laboratories in 7 COMESA Member States in terms of accreditation as minimum in meeting the requirements of the FSMA, Quality Management Systems (QMS) implementation, testing scope and capacity to support the export of agricultural commodities to the US and other countries in the region.

# **MAIN ACTIVITIES**

* Preparation of a survey tool/instrument, based on ISO 17025 criteria, for the laboratories to review their capacity and operations
* In the field, visit the main laboratories servicing the targeted trade flows/value chains in the countries
* Review and evaluation of the current capacity utilization of the laboratories including human resources, operations, environmental conditions and equipment
* Assessment of needs in view of the potential for accreditation
* Preparation of a final terminal report at the end of the contract comprising of all relevant information including conclusions and recommendations.

# **RESULTS**

## **ETHIOPIA**

**Agricultural exports from Ethiopia**

According to the COMESA AGOA Review report February 2019, the top 3 export product groups from Ethiopia with the highest dollar value in 2017 were coffee, tea, and spices at US$963 million (33.6% of total exports), Vegetables at $538.4 million (18.8%) and Oil seeds at $446.3 million (15.6%). The agricultural product exports to the US totalled $174 million in 2017. Leading categories include: coffee, unroasted ($147 million), nursery products ($5 million), spices ($1 million), planting seeds ($502 thousand), and wine and beer ($343 thousand).

In 2008, Ethiopian coffee exported to Japan was found to have residues of three globally banned chemicals i.e. lindane, heptachlor, and chlordane with levels exceeding the Maximum Residue Limits (MRLs). This called for strengthening of laboratories offering pre-export testing as part of conformity assessment. The **A**gricultural Products Quality Monitoring and Testing Laboratory (APQMTL) apesticide residue analytical laboratory was established by the Ministry of Agriculture in 2011, with funding from Japan. The aim was to have it accredited. The equipment in the laboratory include GC-ECD, GC-MS, GC-NPD and HPLC. By the time of the assignment the laboratory was not active and was therefore not assessed. Other laboratories offering testing services to food enterprises include Ethiopian Conformity Assessment Enterprise (ECAE), a public laboratory and Bless-Agri-Food Laboratory a private entity. The gap assessment was carried out for the latter two.

**Ethiopian Conformity Assessment Enterprise laboratory**

**Laboratory overview**

ECAE was established in February 11, 2011 as a federal owned public enterprise, governed by the ministry of Science and Technology. ECAE is at present the major conformity assessment organization in the country providing inspection, laboratory testing and certification services to the public and industries. Its departments include the following:

**Testing laboratories**

* Chemical testing (accredited in honey, oilseeds, cement)
* Microbiological testing (accredited in water, foods)
* Radiation testing

**Certification services**

* Product certification
* System certification accredited by Deutsche Akkreditierungsstelle (DAkkS), in 13 scopes based on ISO 9001: 2008)
* Food safety managements system certification (ISO 22000)
* Environmental management system (ISO:14001)
* Personnel certification

**Inspection services**

* Product inspection and Service inspection

The Laboratory customers include exporters and local traders. It is funded by the government. The assessment was carried out in the chemistry laboratory. The microbiology laboratory is functional but detailed information was not provided.

**Assessment findings**

**Facilities and environmental conditions**

* The facility has stable water and power supplies. A standby generator is in place.
* The sample storage area (space) is not adequate
* Environmental conditions likely to influence the validity of test results have not been documented for some test methods.
* Requirements for facilities and environmental conditions necessary for the performance of the laboratory activities have been documented
* Environmental conditions are monitored, controlled and recorded in accordance with relevant specifications, methods, and procedures or where they influence the validity of results including storage areas for samples, reagents and reference materials, sample preparation and equipment areas
* Access to the laboratory is controlled by electronic locks. Areas with incompatible laboratory activities are separated.

**Human Resources including ongoing training**

* The number of personnel performing laboratory testing is adequate. They meet the minimum academic qualifications, a first degree in the relevant fields. All have been in trained in the requirements of ISO 17025 and ISO 9001.
* Procedures for personnel records are in place including competence evaluation for the performance of specific tests, selection criteria to perform specific tests, training, supervision, authorization and competence monitoring.
* Training needs are determined during management review meetings, internal and external audits, and one to one interview with the personnel. The ongoing training include the requirements of ISO 17025 and ISO 9001. Funding of identified training needs is not adequate. There is need to attach staff in more advanced and accredited laboratories.

**Equipment**

The laboratory is well equipped to test chemical and microbiological contaminants, food composition and additional tests including allergens in raw and processed foods. Table 1 below is a summary of the equipment available in the ECAE laboratory.

**Table 1:** **Equipment available in the ECAE Laboratory, use and condition**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Equipment Name** | **Purpose for which it is used** | **Condition (e.g. Working, not working but serviceable or unserviceable)** |
| 1 | Fat determination apparatus, semi-automated soxhlet apparatus | Fat or Oil content determination | Working  |
| 2 | Polarimeter  | Polarization value determination  | Working |
| 3 | Refractometer  | Brix value and refractive index determination  | Working |
| 4 | Beer analyser set | Full beer parameter like PH, Alcohol, Wort, Colour, CO2, Dissolved Oxygen, Bitterness etc | Working |
| 5 | PH/Conductivity meter | PH value, Conductance | Working |
| 6 | Kjeldhal apparatus set | Total nitrogen and Protein  | Working |
| 7 | Fiber determination apparatus  | Crude fiber  | Working |
| 8 | HPLC | Sugar profile, HMF, Vitamins, Caffeine, Mycotoxins, Veterinary drugs | Working |
| 9 | LC-MS/MS | Mycotoxins, pesticide residue  | Not working but serviceable |
| 10 | GC-MS | pesticide residue | Working |
| 11 | UV-Visible Spectroscopy | Sulphate, Phosphate, Iron, Chloride | Working |
| 12 | Microwave plasma atomic emission spectroscopy (MP-AES) | Minerals (Ca, K, Na, etc.) | Working |
| 13 | ICP-OES | Minerals and heavy metals | Under installation  |
| 14 | Grain analyzer  | Protein, Moisture  | Working |
| 15 | Flour analyzer | Protein, Moisture  | Working |
| 16 | Amylograph | Water absorption capacity  | Working |
| 17 | Calorimeter  | Energy or calorific value | Not working but serviceable |
| 18 | XRF | Mineral as oxide | Not working but serviceable |

* The laboratory has in place records of the equipment that can influence laboratory activities Procedures for handling, transport, storage, use and planned maintenance for the equipment are in place
* Calibration programs for all the measurement equipment are in place.

**Management**

* The laboratory has developed a quality manual, factoring in the establishment, documentation and maintenance of policies and objectives for the fulfilment of the requirements of ISO 17025 standard
* The policies and objectives have been acknowledged at all levels of the laboratory organization
* The objectives have addressed competence, impartiality and consistent operation of the laboratory.
* There is a statement in the quality manual indicating the laboratory management commitment to the development and implementation of the management system and to continually improve it
* Although it was indicated, through interviews, that there was a control of management documents, it was not clear how it was being done.
* The laboratory has not implemented the 2017 version of ISO 17025 and has therefore not established a risk register and procedures for identifying opportunities for improvement.

**Test methods**

The laboratory applies ISO, AOAC and ASTM methods of analysis. Table 2 below is a summary of tests currently carried out in the laboratory.

**Table 2: summary of tests performed in the ECAE laboratory**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sample matrix** | **Parameter tested**  | **Validation data available-Yes/No** | **Accreditation status of test method- Yes/No** |
| Edible Salt  | * Sodium chloride (NaCl)
* Moisture content
* Water insoluble matter
* Iodine
* Alkalinity (as Na2CO3)
* Acid insoluble matter
* Sulphate (as SO4)
 | Yes | Application for Accreditation has been made |
| Gin | * Alcohol content
* Total solids
 | Yes | Application for Accreditation has been made |
| Edible oil | * Acid value
* Peroxide value
* Relative density
* Refractive index
 | Yes | Application for Accreditation has been made |
| Honey | * HMF
* Reducing and none reducing sugars
* Heavy metals
* Pesticide residues

 Veterinary drugs | **Yes except for pesticide residues**. | Application for Accreditation has been made except for pesticide residues |
| Flour | * Moisture
* Protein
* Fat
* Crude fibre
* Ash
* peroxide value
* Iron
* Calcium
* Potassium
* Aflatoxin (Total)
 | Yes | Application for Accreditation has been made |
| Water  | * pH
* TDS
* Chloride
* Sulphate
* Hardness
* Alkalinity
* Calcium
* Magnesium
* Iron
* Potassium
* Sodium
* Copper
* Zinc
 | Yes | Application for Accreditation has been made |

SOPs for the above test methods are in place.

**Standard Operating Procedures**

The laboratory has implemented a QMS and has therefore documented its processes and procedures. However, there are gaps in document control SOPs.

**Quality Assurance**

* Quality assurance procedures include running QC samples and duplicate analysis. Certified reference materials available in the laboratory include those for aflatoxinsB1, B2, G1, G2 and M1, Minerals, Pesticides, Sugars (Sucrose, Fructose, Glucose, Maltose, Turanose), HMF and Veterinary drugs.
* The laboratory participates in PT schemes organized by QUATEST, BIPEA, FAPAS, EAC and SADCMET

**Gaps identified in the ECAE laboratory**

Table 3 below is a summary of gaps identified in the ECAE laboratory

**Table 3: Gaps identified in the ECAE laboratory**

|  |  |
| --- | --- |
| **QMS component** | **Gaps** |
| Facilities and environmental conditions | * The space for sample storage is not adequate.
 |
| Human Resources including ongoing training | * Training in equipment maintenance after procurement is not adequate.
* Exposure of staff in more advanced laboratories and regionally organized forums is required.
 |
| Equipment | * Repair and maintenance service providers are not always available, and their turnaround time affects service delivery negatively
* Personnel training in instrumentation is not adequate.
 |
| Management | Document control procedures are not up to date |
| Test methods | * Allergen testing is not included in the scope.
* The availed list of tests is limited in commodity coverage and does not include priority Ethiopian exports, coffee, tea and spices.
* The safety parameters testing is limited in mycotoxin coverage and does not include residues of veterinary drugs. Test methods for pesticide residues are not validated.
 |
| Standard Operating Procedures | SOPs for document control are not in place. |
| Quality Assurance | Participation in food composition external QCs is limited to ILCs.  |
| Scope of accreditation | Limited in matrix and parameter coverage for important trade commodities.  |

**Conclusions**

* The ECAE laboratory meets the minimum requirements for recognition under the FSMA
* Limitation in space for sample storage can lead to cross contamination. The ISO 17025:2005 clause 5.3 and ISO 17025:2017 clause 6.3 requirements for facilities and environment have been addressed.
* Exposure of personnel beyond the ECAE laboratory would help in improving and introducing practices for improvement of the QMS. The ISO 17025:2005 clause 5.2 and ISO 17025:2017 clause 6.2 requirements for personnel have been addressed
* The laboratory is well equipped to test chemical and microbiological contaminants, food composition and additional tests including allergens in raw and processed foods. The ISO 17025:2005 clause 5.5 and ISO 17025:2017 clause 6.4 requirements for equipment have been addressed
* The management system is adequate for the current scope of work. The ISO 17025:2005 clause 4 and ISO 17025:2017 clause 8.2 requirements for management have been addressed except for document control.
* The laboratory has the capacity to expand test coverage of parameters and commodities to facilitate conformity assessment. The ISO 17025:2005 clause 5.4 and ISO 17025:2017 clause 7.2 requirements for test methods have been addressed.
* Documentation of the quality system meets the requirements of ISO17025 but needs to be improved
* Quality assurance procedures are adequate for the current scope of testing. The requirements of ISO 17025:2005 clause 5.9 and isi17025:2017 clause 7.7 are addressed

**Recommendations**

* Identify/create more space for sample storage
* Dedicate and train specific personnel to oversee equipment maintenance. Review procurement of equipment to address servicing
* Explore opportunities for attachment of personnel in more advanced accredited laboratories and for participation in regionally organised training forums
* Address the requirements for document control in the laboratory.
* Expedite installation of the ICP/OES, include more parameters to be tested with the equipment and plan for method validation.
* Review the services required by exporting enterprises, prioritise introduction of required tests and plan for their validation in preparation for their accreditation. It is recommended that coverage include allergens, food composition parameters e.g. vitamins, and contaminants, both organic and inorganic.

**BLESS Agri Food Laboratory Services PLC**

**Laboratory overview**

The Hilina Laboratory Business Unit was established as a business Centre under Hilina Enriched Foods Processing Centre in 2007. It is a modern commercial food testing laboratory capable of undertaking a wide variety of microbial, chemical and physical tests in food products. Customers include exporters, local traders, farmers, consumers, environmentalists, researchers and relief agencies. Other laboratories in Ethiopia subcontract the laboratory for some tests. Local traders provide the bulk of the work (60 %) followed by exporters (37%). The laboratory has established a QMS based on ISO 17025:2005 and was accredited by the South African National Accreditation System (SANAS) in 2012. To address the increasing demand for the laboratory analytical services, the laboratory is separated from its parent company. Funding is from internally generated revenue, company shareholders and bank loans.

**Assessment findings**

**Facilities and environmental conditions**

* The laboratory has training facilities including conference rooms and accommodation.
* The laboratory building complex is modern and spacious. The water and power supply are adequate.
* Environmental conditions likely to influence the validity of test results have been identified
* Environmental conditions necessary for the performance of the laboratory activities have been documented
* Environmental conditions are monitored, controlled and recorded in accordance with relevant specifications, methods, and procedures or where they influence the validity of results. This has been done for sample, reagent and reference materials storage areas, sample preparation and equipment areas.
* Access to the laboratory is controlled and areas with incompatible activities are separated.

**Human Resources including ongoing training**

* The laboratory has adequate staff with required competences. Those working in the microbiology and chemistry sections are BSc holders in Applied biology and Applied chemistry respectively. The number of personnel is adequate for the current scope of work.
* Procedures and personnel records are in place including competence evaluation for the performance of specific tests, selection criteria to perform specific tests, training, supervision, authorization and competence monitoring
* The laboratory has categorized personnel training into three areas, i.e. mandatory, required and developmental. The Quality team which has members from different departments meet once a year to develop an annual training program based on the categorization and needs.
* The ongoing training includes the requirements of ISO17025:2017.

**Equipment**

BLESS Agri Food Laboratory is equipped for chemical and microbiology testing. However, it requires to invest in an ICPMS to upgrade to modern detection techniques.

**Table 4: Equipment available in Bless Laboratory, use and condition**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Equipment Name** | **Purpose for which it is used** | **Condition (e.g. Working, not working but serviceable or unserviceable)** |
| 1 | Amylograph | Wheat analysis including water absorption capacity | Working |
| 2 | HPLC  | Mycotoxins, Vitamins | Working  |
| 3 | LCMS | Residue Analysis (Pesticide & Veterinary) |  |
| 4 | GC MSMS  | Residue Analysis (Pesticide & Veterinary)  | Working  |
| 5 | AAS  | Minerals and heavy Metals  | Working  |
| 6 | NIR Infrared  | Proximate Analysis  | Working  |
| 7 | 3M Molecular System  | Microbiological Analysis  | Working  |

* Records for equipment that can influence laboratory activities are in place.
* Procedures for handling, transport, storage, use and planned maintenance for each equipment have been established.
* Calibration programs for all the measurement equipment are in place

**Management**

* A quality is in place, factoring in the establishment, documentation and maintenance of policies and objectives for the fulfilment of the requirements of ISO 17025 standard.
* The policies and objectives have been acknowledged at all levels of the laboratory organization
* The objectives have addressed competence, impartiality and consistent operation of the laboratory.
* A statement in the quality manual commits the management to develop and implement the management system and to continually improve it.
* Document control is manual and in place. All original documents are under the custody of the Quality manager. A Document master distribution List which is signed by all recipients is in place.
* The laboratory has procedures for identifying opportunities for improvement, including customer feedback and results of internal and external audits.

 **Test methods.**

The laboratory applies international methods of analysis e.g. AOAC and Codex Alimentarius. Commodities tested include animal feed, spices and herbs, honey, sugar and confectionary, salt, water, soil, edible oil, Cereals, Cereal products and by-products, nuts and nut products and dairy Products. Table 5 below is a summary of tests carried out in the laboratory. Commodities tested.

**Table 5: Summary of parameters tested in the Bless laboratory**

|  |  |  |
| --- | --- | --- |
|  | CHEMISTRY | MICROBIOLOGY |
|  | **Food composition**1. Moisture
2. Protein
3. Fat
4. Ash
5. Fibre
6. Carbohydrate
7. Energy

**Contaminants**1. Aflatoxins B1, B2, G1, G2 and total Pesticide residues
2. Residues of veterinary drugs
 | 1. Coliform,
2. Faecal coliform
3. E-coli,
4. Salmonella
5. Cronobacter Sakazakii
 |

validation data was available including the evaluation of measurement uncertainty. The laboratory was accredited by the time of the assessment. The accreditation was however suspended on 11/04/2019.

**Standard Operating Procedures**

The laboratory has documented the managements and technical documentation. SOPs for procedures and processes are therefore in place.

**Quality Assurance**

* Internal Quality Assurance procedures include use of triplicates, internal quality control samples, spiking, positive controls, negative control, Blanks use of CRMS. External Quality Assurance procedures include participation in PTs and ILCs.
* The laboratory participates in PT schemes provided by the Food Analysis Performance Assessment Scheme (FAPAS) and Laboratory of Government Chemist (LGC) Limited.
* CRMs providers include European Commission joint Research Center and Biosisto B.V. Netherlands.
* The laboratory keeps records for reagents and consumables, their acceptance criteria, stock management and a suppliers list.

**Gaps Identified in the BLESS Agri Food Laboratory**

Table 6 below is a summary of identified gaps in the above laboratory

**Table 6: Identified gaps including compliance with relevant ISO 17025 clauses**

|  |  |
| --- | --- |
| **QMS component** | **Gaps** |
| Facilities and environmental conditions | - |
| Human Resources including ongoing training | - |
| Equipment | ICPMS and LCMSMS required to update technology, modern test methods and include more parameters  |
| Management | - |
| Test methods | Allergen testing is not included. |
| Standard Operating Procedures | In place but continuous improvement is recommended |
| Quality Assurance | Participation in PTs is limited. |
| Scope of accreditation | Accreditation suspended in April 2019. |

**Conclusions**

* At the time of the assessment, the laboratory met the minimum requirements for recognition under the FSMA
* With the current capacity (working area and equipment), more tests, including allergens, can be added to the current scope. The ISO 17025:2005 clause 5.3 and ISO 17025:2017 clause 6.3 requirements for facilities and environment have been addressed.
* The ISO 17025:2005 clause 5.2 and ISO 17025:2017 clause 6.2 requirements for personnel have been addressed
* The laboratory needs to invest in LCMSMS ICOMS equipment. The ISO 17025:2005 clause 5.5 and ISO 17025:2017 clause 6.4 requirements for equipment have been addressed
* The management system is adequate for the current scope of work. The ISO 17025:2005 clause 4 and ISO 17025:2017 clause 8.2 requirements for management have been addressed
* Documentation of the quality system meets the requirements of ISO17025 but needs to be improved
* The requirements of ISO 17025:2005 clause 5.9 and isi17025:2017 clause 7.7 for quality assurance are addressed
* The laboratory has the capacity to host training activities including practical training in food composition and contaminants testing.

**Recommendations**

* Although Bless is a private entity, COMESA can explore ways of establishing a partnership to conduct training in the laboratory if such a need arises for Ethiopia. This may be done by involving the ECAE, which is a public entity.
* The laboratory can consider introducing allergen testing to its scope. The methods can be validated to have them included in the accreditation schedule as the laboratory works towards the re-instatement of the accreditation status

## **KENYA**

**Agricultural exports from Kenya**

According to the COMESA AGOA Review report February 2019, Kenya is among the top 5 US import suppliers from the COMESA region, at $572 million in 2017. The US is ranked 5th among the Country’s top trading partners. Agriculture based exports constituted the highest percentage with coffee, tea, spices contributing $1.7 billion (29% of total exports. Live trees, plants, cut flowers, fruits and nuts were ranked among the top 10 export commodities. In total, agricultural exports were worth $165. Food commodity exports contributed significantly to monetary inflows into the country.

There are several laboratories offering testing services to exporters as part of conformity assessment and in support of HACCP programs. A gap assessment was carried out in three laboratories. They are all represented in the National Food Safety Committee (NFSCC) and are hosted by the following organizations:

* Kenya Bureau of Standards
* Kenya Plant Health Inspectorate Service
* Ministry of Health.

**Assessment findings**

**Kenya Bureau of Standards- Testing Laboratories, Food and Agriculture**

**Laboratory Overview**

The laboratory is a public, regulatory legal entity with the host institution falling under the Ministry of Trade. It is designated to carry out official controls for food quality and safety. It has satellite laboratories in three cities, Mombasa and Kisumu. It serves a wide range of customers including exporters, importers, local traders, farmers, consumers, environmentalists, researchers, relief agencies, subcontractors, and public health inspectors. The laboratory has implemented a quality management system and is accredited by the South African National Accreditation Service (SANAS). Funding is from internally generated revenue, grants, and by donors including the European Union (EU) and Trade Mark East Africa (TMEA)

**Facilities and environmental conditions**

* Sample storage/archiving area is limited.
* The laboratory has stable power and water supply. Environmental conditions likely to influence the validity of test results, including humidity and temperature have been documented.
* Requirements for facilities and environmental conditions necessary for the performance of the laboratory activities have been documented.
* Environmental conditions are monitored, controlled and recorded in accordance with relevant specifications, methods and procedures and where they influence the validity of results. Monitoring records for sample storage, reagent storage, reference materials storage, sample preparation and equipment areas are in place.
* Access to the laboratory controlled is controlled through security vetting of visitors and signage.
* Areas with incompatible laboratory activities are separated

**Human Resource**

* The laboratory personnel meet the required competence criteria to carry out the specific tests in the laboratory.
* Personnel records are in place including those for competence evaluation for the performance of specific tests, selection criteria to perform specific tests, training, Supervision, authorization and competence monitoring.
* A procedure for training needs evaluation is in place
* The laboratory has training programs, but they do not address all the identified needs.

**Equipment**

The laboratory is well equipped to test chemical and microbiological contaminants, food composition and additional tests including allergens in raw and processed foods. Table 7 below is a summary of the available equipment.

**Table 7: KEBS laboratory Equipment list, use and condition**

|  |  |  |
| --- | --- | --- |
| **Equipment Name** | **Purpose for which it is used** | **Condition (e.g. Working, not working but serviceable or unserviceable)** |
| HPLC | Vitamins, sweeteners and mycotoxins | Working |
| ELISA Reader | Mycotoxins | Working |
| FT NIR | Proximate analysis | Working |
| Soxtherm, Multi Stat  | Fat Content, Free Fatty Acids & Acid Value | Working |
| Kjeldhal Distillation Assembly, Tecator Digestion Block & Vapodest Distiller | Protein & Nitrogen Content | Working |
| Muffle furnace | Ash content & Acid Insoluble Ash | Working |
| Milk Fat Extractor | Milk fat content | Working |
| pH Meter - Jenways | pH | Working |
| Pressure Gauge | Volume of Carbonation in carbonated Beverages | Working |
| Drum Hoop Mixer | Homogenization of PT samples | Working |
| Microwave digestor | Sample preparation | Working |
| UV/VIS spectrophotometer | Anion analysis in various products | Working |
| MP-AES | Trace element analysis (entry level) | Working |
| ICP-OES | Trace element analysis in various products | Working |
| ICP-MS | Ultra- trace element analysis in various products | Working |
| GC-MS | Organic compounds in different matrices/products | Working |
| GC-MS/MS | Organic compounds in different matrices/products | Working |
| GC - FID | Congeners in alcoholic beverages | Working |
| GCMS, TRIPPLE QUAD, | Pesticides residue | Working |
| HPLC, UPLC | Benzoic, caffeine, hydroquinone, vitamin c, phthalates. | Working |

* Equipment inventories and specific records are maintained by the specific laboratory units. The laboratory does not use equipment located outside the facility
* Procedures for handling, transport, storage, use and planned maintenance for each equipment are in place.
* Calibration programs for all the measurement equipment are in place.

**Management**

* The laboratory has developed a quality manual, factoring in the establishment, documentation and maintenance of policies and objectives for the fulfilment of the requirements of ISO 17025 standard.
* The objectives have addressed competence, impartiality and consistent operation of the laboratory
* the management has evidence of commitment to the development and implementation of the management system and to continually improve it.
* Access to the relevant management documentation by staff controlled in relation to their responsibilities via a link to the server and password protected entropy.
* The laboratory has established a risk register and has put in place procedures for identifying opportunities for improvement.

**Test methods**

Guidelines and protocols applied by the laboratory include national guidelines, international guidelines including AOAC, Codex, ISO and ASTM. Others include those developed by the European Committee for Standardization (CEN). Table 8 below is a summary of tests carried out in the laboratory.

**Table 8: Summary of Tests offered by the KEBS laboratory**

|  |  |
| --- | --- |
| **Chemistry** | **Microbiology** |
| Contaminants1. Heavy metals
2. Aflatoxins
3. Pesticide residues

Food composition1. Calcium
2. Fat Content
3. Iodine Content
4. Iron
5. Magnesium
6. Manganese
7. Moisture Content
8. Oil Content
9. pH
10. Phosphorous
11. Potassium
12. Selenium
13. Sodium
14. Sugars
15. Ascorbic Acid content
16. Caffeine Content
17. Chlorides
18. Crude Fibre content
19. Crude Protein content
20. Iron
21. Reducing Sugar content
22. Residual Alcohol content
23. Sodium
24. Sodium Chloride
25. Vitamin A as Retinol
26. Vitamin C as Ascorbic Acid
27. Zinc
 | 1. Total Viable Count
2. *Coliforms*
3. *E. coli*
4. *E. coli 0157*
5. *Streptococcus faecalis*
6. *Staphylococcus aureus*
7. *Iron sulphate reducing anaerobes*
8. *Salmonella*
9. *Pseudomonas spp*
10. *Pseudomonas aeroginosa*
11. *Clostridium perfringens*
12. *Moulds*
13. *Yeasts*
14. *Yeast and Moulds*
15. *Vibrio cholerae*
16. *Vibrio parahaemoliticus*
17. *Lactic acid bacteria*
18. *Anti-bacterial Activity*
19. *Wild yeasts*
20. *Hydrogen sulphide producing bacteria*
21. *Thermophilic spores in sugar*
22. *Thermophilic flat sour spores*
23. *Thermophilic anaerobes producing gas other than H2S*
24. *Thermophilic anaerobes producing H2S gas*
25. *Aerobic mesophiles*
26. *Anaerobic mesophiles*
27. *Anaerobic thermophiles*
28. *Aerobic thermophiles*
29. *Anti-microbial value (Disinfectants)*
30. *Listeria monocytogenes*
31. *Campylobacter spp*
32. *Bacillus cereus*
33. *Legionella spp*
34. *Shigella*
35. *Enterobacteriaceae*
 |

Validation data including the evaluation of measurement uncertainty is available for the methods. The current accreditation certificate is on the SANAS website. <https://www.sanas.co.za/af-directory/testing_list.php>

**Standard Operating Procedures**

The laboratory has documented the Standard operating procedures (SOPs)/ protocols for laboratory activities for management and technical activities.

**Quality Assurance**

* The laboratory has implemented quality assurance procedures, internal and external. These include analyses of samples in replicates, spiking with analytes with known concentrations, use of reference materials and participation in PTs/ILCs.
* Reagent and consumables quality are assured by record keeping including those for acceptance criteria, stock management and suppliers lists.
* The laboratory has no GLP certification.

Table 9 below is a summary of the gaps identified in the KEBS laboratory.

**Table 9: Identified gaps in the KEBS laboratory**

|  |  |
| --- | --- |
| **QMS component** | **Gaps** |
| Facilities and environmental conditions | * Sample storage/archiving capacity is not adequate
 |
| Human Resources including ongoing training | * Training programs do not address all the identified needs
 |
| Equipment | - |
| Management | - |
| Test methods | * Mycotoxin testing is limited to aflatoxins. Other mycotoxins including OTA, residues of veterinary drugs PCBs, PAHs are not included in the scope of testing.
* Testing for allergens is not covered
 |
| Standard Operating Procedures | - |
| Quality Assurance | Information on PT/ILC participation not provided |
| Scope of accreditation | Limited to microbiological contaminants and food composition. |

**Conclusion**

* **The KEBS laboratory meets the minimum criteria for recognition under the FSMA**
* The laboratory has the potential to be one-stop for supporting HACCP programs and conformity assessment for agricultural products. However, given the broad mandate and often having to deal with crises samples (e.g. the sugar crises in 2018), meeting the appropriate turnaround time can be challenge.
* The ISO 17025:2005 clause 5.3 and ISO 17025:2017 clause 6.3 requirements for facilities and environment have been addressed.
* The Personnel is competent for the test work they perform. The ISO 17025:2005 clause 5.2 and ISO 17025:2017 clause 6.2 requirements for personnel have been addressed
* The laboratory is well equipped and can expand to include tests required to support HACCP and conformity assessment. There is capacity to include allergen testing. The ISO 17025:2005 clause 5.5 and ISO 17025:2017 clause 6.4 requirements for equipment have been addressed
* The management system is adequate for the current scope of work. The ISO 17025:2005 clause 4 and ISO 17025:2017 clause 8.2 requirements for management have been addressed
* The ISO 17025:2005 clause 5.4 and ISO 17025:2017 clause 7.2 requirements for test methods have been addressed.
* With other laboratories in Kenya, KEBS can play a complementary role to support trade.
* KEBS is currently providing ILC materials and for food composition parameters. It has the capacity to expand to include contaminants

**Recommendations**

* The issue of sample storage/archiving needs to be addressed.
* For maximum utilization of the equipment currently available, the laboratory can consider including more parameters in the testing scope to cover requirements for food composition, contaminants and allergens.
* Expand the accreditation scope to include parameters required for supporting trade and HACCP.
* Work with other food laboratories represented in the NFSCC to identify areas where the labs can collaborate and complement each other.
* Have the current ILCs accredited to have them achieve PT status.
* Identify relevant Commodity/Contaminant combinations for consideration to commence provision of ILCs which can be accredited to PT status.

**Kenya Plant health Inspectorate Service****- Analytical Chemistry Laboratory and Food Safety (ACL)**

**Laboratory overview**

KEPHIS is the National Plant Protection Organization (NPPO) in Kenya. It is under the Ministry of Agriculture, Livestock, Fisheries and Irrigation. The phytosanitary department hosts the COMESA reference laboratories for plant health. The ACL is a section in the KEPHIS structure and is a legal entity. The laboratory is designated to carry out official controls with respect to pesticide residues. Customers include exporters, local traders, farmers, consumers, environmentalists, researchers and the agro-chemical industry. The laboratory has implemented a QMS and is accredited for chemical testing by SANAS. The main source of funding is the government through the ministry of agriculture. Other sources of funding include internally generated revenue from commercial testing and donations from development partners, EU, and USAID

**Facilities and Environment**

* The laboratory has adequate space which allows for expansion of current work area and scope. It has stable power and water supply. Environmental conditions likely to influence the validity of test results, including temperature have been documented.
* Requirements for facilities and environmental conditions necessary for the performance of the laboratory activities have been documented.
* Environmental conditions are monitored, controlled and recorded in accordance with relevant specifications, methods and procedures and where they influence the validity of results. Monitoring records for sample storage, reagent storage, reference materials storage, sample preparation and equipment areas are in place.
* Access to the laboratory is controlled through security vetting of visitors and signage in the building.
* Areas with incompatible laboratory activities are separated.

 **Human Resource**

* The academic qualifications of the laboratory personnel include post graduate, graduate and diploma holders. 26 analysts have a chemistry background while 2 have a microbiology background.
* All the technical personnel have been trained in the requirements of laboratory quality management systems and have met the competence requirements to perform the specific tests.
* The laboratory has implemented procedures and personnel records including competence evaluation for the performance of specific tests, selection criteria to perform specific tests, training, supervision, authorization and competence monitoring.
* The laboratory determines training needs through changes in technology, performance in quality assurance activities, audits and management review meetings. The current training programs include ISO 17025:2017, GLP compliance and ISO 22000.

**Equipment**

The laboratory is well equipped for chemical contaminants testing. For each equipment type, there is an assigned maintenance analyst. For general maintenance there is a dedicated technician who is responsible equipment record keeping. Table 10 below is a summary of equipment, application and status in the chemistry laboratory. The microbiology laboratory became operational in 2018, has the basic equipment but requires strengthening.

**Table 10: KEPHIS-ACL Equipment, application and condition**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Equipment Name** | **Purpose for which it is used** | **Condition (e.g. Working, not working but serviceable or unserviceable)** |
| 1 | LCMSMS (6440)  | Pesticide residue and Mycotoxin | Working |
| 2 | LCMSMS (6490) | Pesticide residue and Mycotoxin | working |
| 3 | ICPMS | Trace analysis (Elemental) | working |
| 4 | GFAAS | Trace analysis (Elemental) | working |
| 5 | UV/Vis | Colorimetric analysis (soil, water, fertilizer’s) | working |
| 6 | GCMSMS SHIMADZU | Pesticide residues and PCBS | working |
| 7 | GCMS Agilent | Pesticide residues and PCBS | WORKING |
| 8 | FAAS | Elemental analysis | working |
| 9 | AGILENT GC | Active ingredient analysis in formulated pesticide products | working |
| 10 | WATERS HPLC | Active ingredient analysis in formulated pesticide products | working |
| 11 | PERKIN ELMER GC | Active ingredient analysis in formulated pesticide products | working |
| 12 | AGILENT HPLC |  | working |
| MICROBIOLOGY LABORATORY |
|  | 1. Sterilizing Autoclave (1)
2. Incubators (2)
3. Oven (1)
4. Water bath (1)
5. Orbital shaker (1)
6. Hotplate Magnetic Stirrer (2)
7. Colony counter (1)
 |

* Equipment inventories and specific records are maintained by the specific laboratory units. The laboratory does not use equipment located outside the facility
* Procedures for handling, transport, storage, use and planned maintenance for each equipment are in place.
* Calibration programs for all the measurement equipment are in place.

**Management**

* The laboratory has operated with a quality management system since the year 2006 when it developed a quality manual, factoring in the establishment, documentation and maintenance of policies and objectives for the fulfilment of the requirements of ISO 17025 standard. It has since been revised severally. Policies and objectives have been acknowledged at all levels of the laboratory organization.
* The objectives have addressed competence, impartiality and consistent operation of the laboratory
* The laboratory management have evidence of commitment to the development and implementation of the management system and to continually improve it
* Access to the relevant management documentation by staff is controlled in relation to their responsibilities through document registers and computer access passwords.
* A risk register has not been developed as it is a requirement in ISO 17025:2017. The laboratory is in the process of transitioning. Procedures for identifying opportunities for improvement include audit findings and management review meetings

**Test methods**

The laboratory applies international testing methods including AOAC, codex Alimentarius, and EPA. Method SOPs have been developed. Table 11 below is a summary of food tests offered by the laboratory.

**Table 11: Summary of tests offered by the KEPHIS laboratory**

|  |  |  |
| --- | --- | --- |
|  | CHEMISTRY | MICROBIOLOGY |
|  | **Contaminants*** Pesticide residues
* PCBs
* Mycotoxins,
* Heavy metals.

**Food composition*** Crude fibre
* Protein
* Oil content
* Moisture content
* Sugar
* Macro elements
 | The following parameters are tested in Agricultural food products (Fruits, Vegetables and Horticultural products), water, milk and milk products.* E. coli/ Coliforms
* Staphylococcus aureus
* Salmonella sp.
* Yeast and moulds
* Total Viable Count (TVC)
 |

* Validation data including the evaluation of measurement uncertainty is available for the methods
* The laboratory is accredited for pesticide residues and heavy metal testing in food. The current accreditation certificate is on the SANAS website. <https://www.sanas.co.za/af-directory/testing_list.php>

**Standard Operating Procedures**

SOPs for management and technical requirements are in place.

**Quality Assurance**

The laboratory has put in place quality assurance procedures, internal and external. Recovery tests, use of CRMs and replicate testing are the internal QC methods applied. The laboratory participates in PT and ILC s shown in table 12 below.

**Table 12: Summary of PTs, ILCs participation by KEPHIS-ACL**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Scheme** | **Provider of PT/ILC/CRM** | **PT/ILC/CRM** | **ACCREDITATION STATUS**  |
| 1 | 109 Pesticides | TestQual  | CRM | YES |
| 2 | Heavy Metals in Fish | FAPAS  | PT | YES |
| 3 | Pesticides residues | EU FVPT-21  | PT | YES |
| 4 | Pesticides residues | NMI  | PT | YES |
| 5 | Aflatoxins  | Texas  | PT | YES |
| 6 | Pesticide residues | FAPAS PT FCCM24-VEG 79 | CRM | YES |
| 7 | Microbiology  | EAC  | ILC | NO |

**Gaps identified in the KEPHIS-ACL.**

Table 13 below is a summary of the gaps identified in the KEPHIS laboratory.

**Table 13: Identified gaps in KEPHIS-ACL.**

|  |  |
| --- | --- |
| **QMS component** | **Gaps** |
| **Facilities and environmental conditions** | * The microbiology laboratory requires refurbishment.
 |
| **Human Resources including ongoing training** | * Training programs do not address all the identified needs.
* The microbiology laboratory requires extra permanent personnel.
* Training in evaluation of measurement uncertainty and decision rules is required
 |
| **Equipment** | The microbiology laboratory requires extra equipment. |
| **Management** | - |
| **Test methods** | Testing of allergens, polycyclic Aromatic Hydrocarbons, residues of veterinary drugs and additional microbiological parameters need to be included in the scope to enable the laboratory to be one-stop for trade facilitation. Other mycotoxins including Ochratoxin A and fumonisins are currently not included in the scope of testing. |
| **Standard Operating Procedures** | No gaps in relation to the current scope of testing and accreditation |
| **Quality Assurance** | Some unaccredited methods are not been validated**.** |
| **Scope of accreditation** | The laboratory needs to expand the scope of accreditation to include mycotoxins, microbiological parameters and the tests proposed for introduction**.** |

**Conclusions**

* **The KEPHIS laboratory meets the minimum criteria for recognition under the FSMA**
* The laboratory has the capacity to be one-stop for food analysis without investing in extra major equipment
* The ISO 17025:2005 clause 5.3 and ISO 17025:2017 clause 6.3 requirements for facilities and environment are addressed.
* The ISO 17025:2005 clause 5.2 and ISO 17025:2017 clause 6.2 requirements for personnel are addressed
* The ISO 17025:2005 clause 5.5 and ISO 17025:2017 clause 6.4 requirements for equipment have been addressed
* Clause 4 of ISO 17025:2005 and clause 8 of ISO 17025: 2017 for management requirements are addressed
* The scope testing is broad but requires expansion to include more microbiological and chemical parameters indicated as gaps in table 13 above. The ISO 17025:2005 clause 5.4 and ISO 17025:2017 clause 7.2 requirements for test methods have been addressed.
* Documentation of the quality system meets the requirements of ISO17025 but needs to be improved
* Quality assurance procedures are adequate for the current scope of testing. The requirements of ISO 17025:2005 clause 5.9 and isi17025:2017 clause 7.7 for quality assurance are addressed

**Recommendations**

* Refurbish the microbiology laboratory to include stainless steel surfaces and more equipment.
* Train and retrain the current personnel in the microbiology laboratory to strengthen it further.
* Continuous training for all the personnel including training in allergen testing
* Expand the scope of testing to include allergens, PAHs, residues of veterinary drugs, additional mycotoxin and expand the scope of microbiological testing
* Validate all methods, currently in use, not accredited.
* Validate methods as they are added to the scope.
* Expand accreditation scope to include parameters currently covered and those to be introduced.
* Work with other food laboratories represented in the NFSCC to identify areas where the labs can collaborate and complement each other.

**National Public health laboratories- Food Safety & Nutrition Reference Laboratory (FSNRL)**

**Laboratory overview**

The laboratory is a legal entity under the Ministry of Health. It is a national reference laboratory for public health. In 2017, 87% of the work volume were surveys in collaboration with Division of Nutrition of the Health Ministry. Public Health officers provided the rest of the analytical work at 12% with walk-in customers providing a small volume. In 2018, Public health officers provided the bulk of samples (98%) while walk-in customers contributed 2%. Funding is by the Kenya Government.

A quality Management System has been implemented and is being improved to meet the requirement s of ISO 17025 as the laboratory prepares for accreditation. Application for accreditation has been made to the Kenya National Accreditation Service (KENAS). Test method validation is underway.

The National Microbiology Reference laboratory (NMRL) collaborates with FSNRL and also falls under the National Public health Laboratories. It is accredited to ISO 15189 by KENAS. It’s testing services are medical oriented, but it covers some food safety parameters.

**Facilities and Environment**

* The FSNRL was five years ago refurbished with funds from the world bank. It’s location in the same area with the National Referral hospital guarantees stable power and water supply. The current work space is adequate for the current scope of work. Implementation of a quality management system is under way and environmental conditions likely to influence the validity of test results, including temperature have been documented.
* Requirements for facilities and environmental conditions necessary for the performance of the laboratory activities have been documented.
* Environmental conditions are monitored, controlled and recorded in accordance with relevant specifications, methods and procedures and where they influence the validity of results. Monitoring records for sample storage, reagent storage, reference materials storage, sample preparation and equipment areas are in place.
* Access to the laboratory is controlled through security vetting of visitors and signage.
* Areas with incompatible laboratory activities are separated.

**Human Resource**

* The laboratory has 9 analysts engaged on permanent terms. They meet the required academic qualifications, a first degree in chemistry and computer literacy. Competence evaluation is under way as the laboratory is in the process of implementing a quality management. The relevant SOPs, Training and competency and Personnel requirements are in place
* Training needs are documented when new methods, equipment and personnel are introduced. Other needs are identified during assessments, internal audits and through customer complaints.
* Ongoing training programs include training in the implementation of ISO 17025:2017 standard.

**Equipment**

Table 14 below is a summary of the equipment available in the FSNRL

**Table 14****: NPHL- FSNRL Equipment, application and condition**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Equipment Name** | **Purpose for which it is used** | **Condition (e.g. Working, not working but serviceable or unserviceable)** |
| 1 | ELISA Reader | Total aflatoxins in cereals and pulses | Working |
| 2 | GC-MS | Determination of ethanol and methanol in alcoholic beverages | Working |
| Pesticide residues | Working but accessory required |
| 3 | HPLC | Preservatives | Working but micro filters required |
| Vitamin A | Working but accessory required |
| Aflatoxin analysis | Working but reagents required |
| 4 | AAS | Quantitative determination of chemical elements in water | not working but serviceable |
| Heavy metals |
| 5 | UV-VIS Spectrophotometer | Vitamin A, Fe and Zn in flour | Working |

* The laboratory has records of the equipment that can influence laboratory activities including Calibration certificates, equipment maintenance and service records.
* Procedures for handling, transport, storage, use and planned maintenance for each equipment are in place.
* Calibration programs for measurement equipment are in place.

**Management**

* The laboratory has developed a quality manual, factoring in the establishment, documentation and maintenance of policies and objectives for the fulfilment of the requirements of ISO 17025 standard.
* The objectives have addressed competence, impartiality and consistent operation of the laboratory.
* A statement by the management of commitment to the development and implementation of the management system and to continually improve it is in place.
* Access to the relevant management documentation by staff is controlled in relation to their responsibilities.
* A Laboratory Information Management System (LIMS) is in place. Access to relevant segments by different staff by password. Relevant Documents are at points of use and a register is in place for those issued to specific personnel**.**
* **T**he laboratory has established a risk register.
* A procedure for identifying opportunities for improvement was being developed.

**Test methods**

The laboratory employs methods described in the Food, Drugs and Chemical Substances Act (Cap. 254), AOAC, Codex Alimentarius, WHO and manufacturers guidelines. Table 15 below is a summary of tests offered by the laboratory.

**Table 15: Summary of tests offered by FSNRL**

|  |  |  |
| --- | --- | --- |
|  | CHEMISTRY | MICROBIOLOGY |
|  | **Contaminants*** Heavy metals
* Total aflatoxins in cereals, pulses and peanut butter

**Food composition*** Potassium Iodate in table salt
* Ethanol, Methanol, and total acidity in alcoholic beverages
* copper, lead, iron, zinc, calcium and magnesium in water
* sodium, potassium, and lithium in water
* Formalin and Hydrogen peroxide in milk
* Vitamin A, Acid value, Peroxide value in Edible Fats and Oils
* Preservatives, (Sodium benzoate, Potassium sorbate) in juices.
* Zinc and Iron in flour
* Vitamin A in flour
 | * The National Microbiology Reference laboratory (NMRL) offers bacteria tests in food and water.
 |

Validation data for the test methods is not in place. However, that for aflatoxin analysis is in progress. The laboratory has been participating in PTs for the parameter in maize with satisfactory results.

**Standard Operating Procedures**

The standard operating procedures have been developed. However, they are undergoing validation as the laboratory is preparing for assessment by the accrediting body.

**Quality Assurance**

The laboratory has developed an SOP for assuring the validity of analytical results. Monitoring of the validity is by Internal Quality Control- Where QCs are run per set of samples, use of Blanks and Replicate samples. External Quality Control is by participation in a PT schemes. Table 16 below is a summary of PT/ILC scheme participation.

|  |  |  |
| --- | --- | --- |
| **Reference material** | **Service provider** | **Accreditation**  |
| APTECA PT (aflatoxin) | APTECA | YES |
| EAC PT (No food safety parameters) | EAC | NO |
| FAPAS PT (aflatoxin) | FAPAS | YES |

**Table 16: summary of PT/ILC scheme participation**

The laboratory has no GLP certification

**Gaps identified in the NPHL- FSNRL**

Table 17 below is a summary of the gaps identified in the NPHL- FSNRL laboratory.

**Table 17: Gaps in NPHL- FSNRL**

|  |  |
| --- | --- |
| **QMS component** | **Gaps** |
| Facilities and environmental conditions | - |
| Human Resources including ongoing training | Technical training through attachment in more advanced laboratories which are equipped with advanced equipment and have more experienced personnel.  |
| Equipment | The following major equipment are required for modernization methods and widening of testing scope* LCMSMS
* GCMSMS
* ICPMS
 |
| Management | - |
| Test methods | * Allergen testing is not in place.
* Testing of chemical contaminants is limited. Pesticide residues, residues of veterinary drugs, mycotoxins other than aflatoxins, PCBs, PAHs are not in the scope.
* The methods in use have not been validated.
 |
| Standard Operating Procedures | SOP development is ongoing |
| Quality Assurance | * Internal QC programs are in place.
* There is a challenge in accessing CRMs
* Participation in PT is limited and only includes Aflatoxin and food composition schemes.
 |
| Scope of accreditation | Laboratory is not accredited |

**Conclusions**

* **The laboratory does not meet the minimum requirement (accreditation) for approval under the FSMA. However, it has the potential since it has implemented a QMS.**
* The ISO 17025:2005 clause 5.3 and ISO 17025:2017 clause 6.3 requirements for facilities and environment have been addressed.
* Personnel competence meets the minimum requirements. The ISO 17025:2005 clause 5.2 and ISO 17025:2017 clause 6.2 requirements for personnel have been addressed
* The equipment currently available is not adequate for continuous service delivery and introduction of new test methods. Newer models are required. However, The ISO 17025:2005 clause 5.5 and ISO 17025:2017 clause 6.4 requirements for equipment have been addressed
* The current management is aggressively driving the laboratory towards implementing a QMS which will place it in a position to play a complementary role in supporting HACCP programs and conformity assessment. The ISO 17025:2005 clause 4 and ISO 17025:2017 clause 8.2 requirements for management have been addressed.
* The scope of testing for contaminants and food composition is limited. The laboratory is strong in the analysis of aflatoxins, having benefited from previous capacity building by COMESA. The ISO 17025:2005 clause 5.4 and ISO 17025:2017 clause 7.2 requirements for test methods have not been addressed.
* The microbiology laboratory is a separate entity and is biased towards medical testing, hence a limitation in covering food safety.
* The laboratory has a challenge in equipment maintenance.
* Participation in PTs is limited.

**Recommendations**

* Technical training of personnel, in testing and instrumentation, through attachment in more advanced accredited laboratories which are equipped with advanced equipment and have more experienced personnel is recommended.
* The laboratory needs to invest in more advanced equipment including an LCMSMS, GCMSMS and ICPMS
* The laboratory should urgently develop method validation plans, prioritise tests to be validated and commence the validation before the planned assessment by the accreditation body. It needs to expedite the accreditation process.
* More PT schemes should be identified to expand on the current coverage.

## **MADAGASCAR**

**Agricultural exports from Madagascar**

According to the COMESA AGOA Review report February 2019, the US is the leading destination for exports from Madagascar. The current potential for food-based products export to this market comprises of shrimps and prawns (USD 16M), Tunas (USD 7.6M), essential oils (USD 6.3M), vanilla (USD 133M), cloves (USD11.6M) and pepper (USD 2.1M). Others include fruit puree and honey. These products require processing or semi-processing before they can be exported, hence the need for laboratory services to support HACCP systems implementation by food- based enterprises. The following two laboratories were recommended for assessment with respect to compliance with the FSMA requirements and recognition to support enterprises FBOs HACCP systems and conformity assessment:

* Laboratoire d’Analyse et de Contrôle des Aliments et des Eaux (LACAE) hosted by Centre National de Recherches sur l’Environnement (CNRE)
* Laboratoire d’Hygiene des Aliments et de l’Environnement (LHAE)

The LCAE laboratory is public while LHAE is private. The private laboratory declined to be assessed. The exercise was therefore carried out for LACAE only.

**Assessment findings**

**Laboratory overview**

The laboratory is hosted by the Centre National de Recherches sur l’Environnement (CNRE) Customers include exporters, local traders, farmers, Consumers, environmentalists, researchers and the food industry. Local traders and exporters constitute the largest customer base, submitting 83% of the total number of samples. Samples from the food industry include raw materials and finished products, i.e. cereals, fish meal, baby foods and other processed foods. Water is analysed for environmental pollutants. The laboratory has not implemented a Quality Management System. Funding is from the central government.

**Facilities and environmental conditions**

* Power and water supply are adequate
* The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities are documented only in the specific method SOPs.
* Although the laboratory personnel indicated that environmental conditions are monitored, controlled and recorded in accordance with relevant specifications, methods, and procedures or where they influence the validity of results, there were no supporting records.
* Access to the laboratory is controlled by indicative signage
* Areas with incompatible laboratory activities are separated in the chemistry laboratory. The microbiology laboratory a different entity.

**Human Resource**

* The technical personnel include 14 Degree holders and 3 technicians. Qualifications include Food chemistry, Environmental Chemistry or Biochemistry. The academic qualifications are adequate for the scope of testing carried out in the laboratories.
* From the discussions with some of the analysts, they were competent to perform the specific tests although there were no records of competence evaluation.
* Although the laboratory manager indicated there are procedures for competence evaluation for the performance of specific tests, selection criteria to perform specific tests, training, Supervision, authorization and competence monitoring, there were no supporting records
* The laboratory has no procedure for training needs assessment. Individual personnel communicate their needs to the head of the laboratory. However, at the time of assessment, metrology had been identified as an area where personnel were to be trained in as the country has no department responsible for calibration services.

**Equipment**

Most of the equipment in the Madagascar laboratory is old some unserviceable. Table 18 below is a summary of the equipment, including the status.

**Table 18: Equipment list, application and condition**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Equipment Name** | **Purpose for which it is used** | **Condition (e.g. Working, not working but serviceable or unserviceable)** |
| 1 | Atomic Absorption Spectrometers 1. Thermo SOLAAR M series
2. Varian Spectra AA.20
 | Mineral analysis mainly heavy metals including Cadmium, Chromium, Lead and Manganese | * The Thermo AAS was not working.
* The Varian AAS was working in the flame mode. The graphite furnace and cold vapour systems were not working
 |
| 2 | Gas chromatographs1. Varian 3300
2. Thermo finnigan trace
 | Polycyclic aromatic hydrocarbons in environmental samples  | 1 working and one breakdown but repairable |
| 3 | HPLCs1. Agilent 1100
2. Thermo
 | Food additives, vitamins, food colouring and mycotoxin | 2 have broken down but are reparable |
| 4 | UV spectrophotometer | Phosphates, nitrates and nitrites, and nutrition composition. | Working |
| 5 | Infrared spectrometer | Hydrocarbons in environmental sample | Working |

**Management**

The laboratory manager indicated that a quality manual based on ISO17025:2005 was in place but needs to be aligned to the 2017 version. The management documentation was not in place. There was no evidence of internal audits, management reviews, and corrective actions among other issues required to be addressed in the management system.

**Test methods**

The laboratory applies Association of Official Analytical Chemists (AOAC) and Codex Alimentarius methods. They also apply protocol offered by France, and the International Atomic Energy Agency (IAEA). Table 19 below is a summary of tests offered by the laboratory.

**Table 19: Summary of tests carried out in LACAE**

|  |  |
| --- | --- |
| **Chemistry** | **Microbiology** |
| * Determination of nitrogen for the calculation of protein content
* Determination of raw ash content in food samples
* Determination of raw fat
* Determination of Calcium and Phosphorus
 | **Food***Escherichia coli**Total mesophile flora**Chlostridiumporifringens**Coliforms (total and thermotolerant)**Sulphito reducing bacteria (anaerobic)**Molds and yeast**Bacillus serius***Water***Clostridium porfringens**Coliforms (total and thermotolerant)**Fecal streptococus**Revintifiable microorganisms (@22 and 37degrees centigrade**Staphylococus aureus* |

There was no evidence of method verification or validation.

**Standard Operating Procedures**

The only available SOPs were those for analytical methods. Others required in a quality system were not available.

**Quality Assurance**

* The quality assurance procedures employed in the laboratory include use of control charts, blanks and Certified Reference Materials, retained materials for reference and participation in Proficiency testing
* For environmental analysis, control charts, participation in proficiency testing, interlaboratory comparisons and replicate testing procedures are employed to monitor laboratory performance.
* The laboratory participated in the Southern African Development Community Cooperation in Measurement Traceability (SADCMET)/Waterlab and IAEA PT schemes in 2017. There are plans to re-introduce in PTs organized by BIPEA-France. There was no participation in PTs in 2018.

**Gaps identified in LACAE**

Table 20 below is a summary of the gaps identified in LACAE

**Table 20: Gaps in LACAE**

|  |  |
| --- | --- |
| **QMS component** | **Gaps** |
| Facilities and environmental conditions | QMS requirements not fulfilled |
| Human Resources including ongoing training | * There is no procedure for identifying training needs.
* No ongoing training programs except one in metrology
* QMS requirements not fulfilled
 |
| Equipment | * The equipment models in the laboratory are relatively old and cannot achieve the required sensitivity for trace analysis of chemical contaminants, e.g. the Varian 3300 GC is a 2006 model
* Masses for balance verification, balances, refrigerators, freezers and ovens are not calibrated
* The only verification masses available were the 200gm and 50gm which do not cover the range of measurements carried out in the laboratory.
* There are no calibration services available in the country.
* There are no equipment maintenance services in the country.
* QMS requirements not fulfilled
 |
| Management | Documentation of processes and procedures was not in place  |
| Test methods | * Currently, the laboratory has no capacity to test chemical contaminants due equipment age and breakdowns
* Test method SOPs are not in place.
* The test methods currently used have not been validated.
* The microbiology laboratory has adequate scope and capacity
 |
| Standard Operating Procedures | The laboratory has no QMS in place and has therefore not developed SOPs |
| Quality Assurance | Participation in PTs is limited to environmental analysis and is not consistent. |
| Scope of accreditation | The laboratory has no accreditation |
| Others | Accessing laboratory reagents and consumables  |

**Conclusion**

* LACAE does not meet the minimum requirement for recognition under the FSMA
* The space available in both the chemistry and microbiology laboratories is adequate for food composition and safety testing. The ISO 17025:2005 clause 5.3 and ISO 17025:2017 clause 6.3 requirements for facilities and environment have not been addressed.
* Although the personnel have adequate academic qualifications, the ISO 17025:2005 clause 5.2 and ISO 17025:2017 clause 6.2 requirements for personnel have not been addressed
* The laboratory equipment is old and needs replacement. Maintenance services are not available in the country and this impacts on repair turnaround time. None of the requirement s of ISO17025:2005 clause 5.5 and ISO17025:2017 clause 6.4 have for equipment have been met.
* Although the laboratory has an organogram, the requirements of ISO17025:2005 clause 4 and ISO17025:2017 clause 8.2 have not been met. Documentation of the management system is inadequate.
* The Chemistry laboratory scope is adequate for food composition testing. However, testing of chemical contaminants needs to be implemented using modern methods. The ISO 17025:2005 clause 5.4 and ISO 17025:2017 clause 7.2 requirements for test methods have not been addressed.
* Measurement traceability cannot be guaranteed as there were no calibration records for the verification masses, balances, ovens and refrigerators.

**Recommendations**

* Initiate the commencement of Documentation of procedures and activities in the laboratories as part of preparation for QMS implementation and subsequent application for accreditation
* New and modern equipment is required for the laboratory to serve the food export industry and to start working towards method validation and subsequent accreditation. The environment required for any new equipment will have to be evaluated and created before purchase.
* Attachment of personnel in relevant accredited laboratories is recommended as a starting point followed by training in the requirements of ISO17025:2017. This will help in the initiation of the implementation of a QMS and the operation of more advanced equipment.
* A procedure for training needs assessment needs to be put in place.
* For the laboratory to implement modern methods of food contaminant analyses it needs to invest in major equipment, i.e. GC-MSMS, LC-MSMS and ICP-MS

## **MAURITIUS**

**Agricultural exports from Mauritius**

In 2017 Mauritius was the United States' 104th largest supplier of goods imports. The main agricultural products exported to the US by the country during the same period included: raw beet & cane sugar ($11 million), spices ($820 thousand), sugars, sweeteners, bee based. ($85 thousand), wine and beer ($48 thousand), and tea, including herb ($10 thousand). U.S. total imports of agricultural products from Mauritius totalled $12 million. Despite the relatively small volume of food-based exports, quality laboratory services are important in facilitating trade within and outside COMESA. A gap assessment was carried out in the Food Technology Laboratory (FTL).

**Assessment findings**

**Laboratory overview**

The Food Technology Laboratory (FTL) is a public legal entity providing analytical, advisory and technical services in the fields of food science and technology. It falls under the Ministry of Agro-Industry and Food Security. It supports research work at both national and regional levels. Laboratory customers include exporters (pineapple), local traders, farmers, consumers, environmentalists (dead fish), Researchers/Extension, subcontractors and regulatory bodies. Farmers contribute the highest volume of work, **≈**80%, local traders and exporters contribute **≈**15% and **≈**4% respectively. Sample matrices tested for safety include fish and fishery products, honey, spices, nuts and feeds. Funding of the laboratory is by the Central government. FTL is designated by COMESA as a reference laboratory for food safety. The laboratory has implemented a Quality management System and is accredited to ISO17025:2005 by the National Accreditation Board for Testing and Calibration Laboratories (NABL), India.

**Facilities and environmental conditions**

* The laboratory has stable power and water supplies. A standby generator and adequate water storage facilities are in place.
* Environmental conditions likely to influence the validity of test results have been identified and documented.
* Measures are taken to control and monitor specific environmental conditions (temperature, RH, lighting, humidity, power supply) and records are maintained
* Incompatible works activities are separated
* The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities have been documented in the Quality Manual.
* The laboratory monitors, controls and records environmental conditions in accordance with relevant specifications, methods, and procedures or where they influence the validity of results.
* Access to the laboratory is controlled by digital and is limited to technical staff and authorized visitors. The laboratory has installed digital door-lock. Visitors must sign a confidentiality form before accessing the laboratory.

**Human Resource**

* FTL has adequate staff with relevant competences, academic qualifications and experience. Those working in the microbiology laboratory are trained in microbiology, while those in the chemistry laboratory are trained in Chemistry and food science
* The laboratory has procedures and personnel records documented in the quality manual. FTL policy requires that all personnel who are involved in testing be given training followed by competency assessment
* Training needs are identified based on the strategic goal of FTL, continuous improvement of laboratory services and personnel performance appraisal. Training can be local, in-house or overseas. The current proposed training (2019) includes validation for Pesticide residue analysis, training in mycotoxin analysis and implementation of ISO 17025:2017

**Equipment**

The laboratory is well equipped to test a wide range of contaminants, chemical and microbiological. Table 21 below is a summary of the available equipment, application and condition

**Table 21: Equipment list, application and condition**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Equipment Name** | **Application** | **Condition (e.g. Working, not working but serviceable or unserviceable)** |
| 1 | Distillation unit (Kjeltec) | TVB-N | Working |
| 2 | AAS (graphite furnace and flame-based atomization) | Heavy Metal | Working |
| 3 | HPLCs | Histamine, Mycotoxins and Sugars | Working |
| 4 | LCMSMS/GCMSMS/ UPLCMSMS | Pesticide residues | Not Working but serviceable |
| **Microbiology Laboratory** |
| 5 | Precision balances | Weighing of media and sample weighing  | Working |
| 6 | autoclaves | Sterilization of media and glassware, separate autoclave for decontamination | Working |
| 7 | Incubators (set and calibrated at specific temperature for specific test analysis | Incubation of inoculated broth and plates | Working |
| 8 | Laminar flows hoods | To maintain sterility for sample preparation, inoculation. | Working |
| 9 | Biosafety cabinets grade 2 | To maintain sterility and prevent contamination during analysis procedure | Working |
| 10 | Lab grade refrigerators/freezers for each categories of laboratory samples | Storage of samples, inoculated plates/broth awaiting further testing activities | Working |
| 11 | microscopes | Examination of microorganism | Working |
| 12 | Digital thermometers with probe | Monitoring temperature of incubators, water bath, refrigerators/freezers | Working |
| 13 | Infrared thermometers | Recording temperature of laboratory sample | Working |
| 14 | Set of weights | Monitoring of precision balance | Within the required accuracy level |

* Records for the equipment that can influence laboratory activities are in place as per procedure Equipment MSP 16 of the Quality Manual. The same procedure covers handling, transport, storage, use and planned maintenance for each equipment.
* Calibration programs for all the measurement equipment are in place, e.g.
* **Annual Calibration**: Precision balance, Hygrometer, Digital thermometers,
* **Biannual calibration**: incubators, biosafety cabinets, high temperature data loggers for autoclave

**Management**

* The laboratory has implemented the requirement of the ISO17025:2005. Transitioning to the 2017 version had commenced. A quality manual, factoring in the establishment, documentation and maintenance of policies and objectives for the fulfilment of the requirements of ISO 17025 standard was in place, with policies and objectives having been acknowledged at all levels of the laboratory organization
* The objectives have addressed competence, impartiality and consistent operation of the laboratory
* There was evidence of commitment to the development and implementation of the management system and to continually improve it. Audit plans are in place.
* Access to the relevant management documentation by staff is controlled in relation to their responsibilities through the provision of passwords to access required, relevant documents relevant to their specific tasks.
* The laboratory has established a risk register and it is being updated.
* Opportunities for improvement are identified through internal audit and management review reports, corrective actions, customer feedback and PT results.

**Test methods**

The test methods applied in the laboratory include International (AOAC and Codex Alimentarius). Others include British Standards methods, ISO, and from Journals of Chromatography.

The FTL carries out a wide range of tests on agricultural commodities. Table 22 below is a summary of the scope of testing.

**Table 22: Summary of tests performed in FTL**

|  |  |  |
| --- | --- | --- |
|  | CHEMISTRY | MICROBIOLOGY |
|  | * Histamine
* Cadmium, Lead, Mercury
* Total Volatile Base Nitrogen (TVB-N)
* Aflatoxins (B & G)
* Pesticide Residues
* Brix
* Moisture content
 | 1. *E coli ATCC 25922*
2. *Staphylococcus aureus ATCC 6538*
3. *Enterococcus faecalis ATCC 29212*
4. *Saccharomyces cerevisiae ATCC 9763*
5. *Streptococcus pyogenes ATCC 19615*
6. *Salmonella enterica sv enteritidis ATCC 13076*
7. *Salmonella typhimurium ATCC 14028*
8. *Listeria monocytogenes ATCC 7644*
9. *Listeria innocua ATCC 33090*
10. *Rhodococcus equi ATCC 6939*
11. *Bacillus cereus ATCC 11778*
12. *Vibrio parahaemolyticus ATCC 17802*
13. *Pseudomonas aeruginosa ATCC 27853*
14. *Proteus mirabilis ATCC 29906*
15. *Campylobacter jejuni ATCC 33291*
16. *Clostridium perfringens ATCC 13124, SLV 442*
17. *Staphylococcus aureus ATCC 25923*
18. *Enterobacter aerogenes ATCC 13048*
19. *Listeria ivanovii ATCC 19119*
 |

The laboratory has documented all method SOPs. Validation data for the accredited methods is place. Validation of the unaccredited methods, including pesticide residue analysis in fruits and vegetables, Sugars, EC, pH, Moisture, ash in honey is in progress. The accreditation schedule is available on the NABL website <https://www.nabl-india.org/>

**Standard Operating Procedures**

As an accredited laboratory, FTL has documented its applicable SOPs, both management and technical. For the unaccredited methods, SOPs are in place and method validation is ongoing.

**Quality Assurance**

Quality Assurance procedures, internal and external, are in place. Validity of test results is monitored by use of blank controls, PT, use of positive and negative controls.

The performance in microbiological PTs was satisfactory for all the schemes and parameters.

**Gaps identified in FTL**

Table 24 below is a summary of the gaps identified in FTL

 **Table 23: Gaps identified in FTL**

|  |  |
| --- | --- |
| **QMS component** | **Gaps** |
| Facilities and environmental conditions | - |
| Human Resources including ongoing training | * Technical training through attachment in more advanced laboratories equipped with advanced equipment.
 |
| Equipment | * Availability of equipment maintenance and repair service providers.
* Equipment for organic contaminants is not adequate leading to stoppage of work when there is a breakdown considering the limitation in availability of labs for subcontracting.
* An ICPMS equipment is required
 |
| Management | - |
| Test methods | * Allergen testing is not in place.
* Testing of chemical contaminants is limited. Residues of veterinary drugs, PCBs and PAHs are not in the scope.
 |
| Standard Operating Procedures | - |
| Quality Assurance | -  |
| Scope of accreditation | The scope of accreditation for chemical methods and does not include organic contaminants except for aflatoxins. |

**Conclusions**

* The laboratory meets the minimum requirement (accreditation) for approval under the FSMA
* The facility is adequate for the current scope of work and can accommodate extra testing. The ISO 17025:2005 clause 5.3 and ISO 17025:2017 clause 6.3 requirements for facilities and environment have been addressed.
* The personnel are qualified to conduct test work. However, they need to be attached to more advanced laboratories for exposure and identification of opportunities for improvement. The ISO 17025:2005 clause 5.2 and ISO 17025:2017 clause 6.2 requirements for personnel have been addressed
* Extra equipment, ICPMS and duplication of the existing equipment (LCMSMS) is necessary considering the limitation in availability of labs for subcontracting in case of breakdowns. The ISO 17025:2005 clause 5.5 and ISO 17025:2017 clause 6.4 requirements for equipment have been addressed
* The ISO 17025:2005 clause 4 and ISO 17025:2017 clause 8.2 requirements for management have been addressed.
* The laboratory has the capacity to introduce new work areas including veterinary drug residue and allergen testing. The ISO 17025:2005 clause 5.4 and ISO 17025:2017 clause 7.2 requirements for test methods have been addressed.
* Quality assurance procedures are in place. However more PT/ILC schemes for chemical testing should be included. The requirements of ISO 17025:2005 clause 5.9 and isi17025:2017 clause 7.7 for quality assurance are addressed.
* The scope of accreditation is narrow for chemical contaminants

**Recommendations**

* Explore opportunities for exposing personnel to more advanced laboratories.
* Procurement of additional equipment, ICP/MS and LCMSMS
* Expand the scope of testing to include residues more organic contaminants including veterinary drugs and allergens
* Include more PT/ILC schemes in external QC activities
* Expand scope of accreditation in chemical testing

## **RWANDA**

**Agricultural exports from Rwanda**

Rwanda generates more than 70% of the country’s export revenues from food exports. The country earned a total of US$22 million from agricultural products exports to the US in 2017. The leading exports categories included; coffee, unroasted ($20 million), tea, including herb ($503 thousand), tree nuts ($427 thousand), processed fruit & vegetables ($219 thousand), and essential oils ($10 thousand). There is a great opportunity for Rwanda to increase exports to US, especially in value added processed certified organic agricultural products, hence the need to have laboratories which meet the FSMA requirements and which can support HACCP programs and conformity assessment of food products. A gap assessment was carried out for the National Quality Testing Laboratory in the Rwanda Standards Board (RSB).

**Assessment findings**

**Laboratory overview**

The laboratory is a legal entity and a part of RSB which is designated by the State to be a competent Authority. RSB is a public institution with a regulatory role and is designated to carry out official controls. The highest volume of services by the laboratory is to local traders, 92%. Services to exporters constitute 3.2 of the services while consumers and researchers’ requests constitute a small percentage. Funding is from the central government. The laboratory is accredited by the Dutch Accreditation Council, RAAD VOOR ACCREDITATIE (RvA**)** for Microbiological and Inorganic analyses in drinking water, food and feed.

**Facilities and environmental conditions**

* The RSB recently modified a spacious building to house laboratory activities. The space is adequate for the separation of incompatible activities. Stable water and power supply are in place.
* Environmental conditions likely to influence the validity of test result have been identified. The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities have been documented. Environmental conditions, e.g. oven and refrigerator temperatures, are monitored, controlled and recorded in accordance with relevant specification, methods and procedures and where they influence the validity of results.
* Access to the laboratory is controlled by use of appropriate signage.

**Human Resource**

* The National Quality Testing Laboratory has adequate staff with relevant competences, academic qualifications and experience.
* Those working in the microbiology laboratory are trained in microbiology, while those in the chemistry laboratory are trained in chemistry and food science.
* The laboratory has implemented the requirements of ISO17025 and therefore has procedures and personnel records for competence evaluation, competence for the performance of specific tests, selection criteria to perform specific tests, training, supervision, authorization, competence monitoring.
* A procedure for training needs assessment is in place. Continuous training is in place but is not adequate.

**Equipment**

**The laboratory is well equipped for chemical and microbiology testing.**

All the equipment is in working condition except for the Post Column Delivatizer for the analysis of aflatoxin M1. Table 24 below is a summary of the equipment available in the laboratory.

**Table 24: Summary of equipment in the RSB National Quality Testing Laboratory**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Equipment Name** | **Purpose for which it is used** | **Condition (e.g. Working, not working but serviceable or unserviceable)** |
|  | GC FID | Ethanol, methanol, acetaldehyde and higher alcohols | Working |
|  | GC Trace Ultra – DSQ II (GC/MS) | PCBs and PAH | Working |
|  | GC Triple Quadrupole(GC/MS/MS) | Pesticide residues | Working |
|  | LC Triple Quadrupole(LC/MS/MS) | Veterinary drugs and illegal dyes | Working |
|  | Fibertec System 1020-1021 | Fiber content | Working |
|  | NIRS DS 2500 | Moisture, ash, fibre, fat and protein content | Working |
|  | MilkoScan Minor | Milk composition | Working |
|  | MilkoScan FT120 | Milk composition | Working |
|  | TLC Scanner 3 | Aflatoxin B1, B2, G1 and G2 | Working |
|  | Automatic TLC Sampler 4 | Aflatoxin B1, B2, G1 and G2 | Working |
|  | TLC Visualizer | Aflatoxin B1, B2, G1 and G2 | Working |
|  | HPLC UV-Fluorescence Detector | Aflatoxin M1 | Working |
|  | Post Column Delivatizer | Aflatoxin M1 | Not Working |
|  | SKALAR SAN ++ | Nitrates, nitrates, cyanide, fluoride, chlorides, sulphates, phosphates | Working |
|  | AAS PerkinElmer, AAnalyst800 | Analysis of metals | Working |
|  | Flame photometer, JENYWAY | Analysis of sodium and potassium | Working |
|  | Refractometer KRUSS, SN:361040066 |  Brix and sugars content | Working |
|  | Refractometer Mettler Toledo, RE40D | Brix and sugars content | Working |
|  | Polarimeter Rudolph Research Analytical | Polarity  | Working |
|  | TDS/ Conductivity meter JENYWAY, SN:1121 | TDS and conductivity | Working |
|  | UV – vis Spectrometer Thermo, SA3S072006 | Planning for formaldaldehyde analysis  | Working |
|  | Turbidity meter HACH2100AN | Turbidity | Working |
|  | ICP – MS 7900 Agilent  | Analysis of metals | Working |
|  | Automatic titration system Radiometer | Alkalinity in water | Working |

Equipment records are in place, including procedures for handling, transport, storage, use and planned maintenance. Calibration programs for measurement equipment are in place.

 **Management**

* The laboratory has implemented the requirements of ISO17025 standard and has therefore developed a quality manual, factoring in the establishment, documentation and maintenance of policies and objectives for the fulfilment of the requirements.
* The objectives have addressed competence, impartiality and consistent operation of the laboratory.
* Access to documents by staff is controlled by use of passwords. Opportunities for improvement are identified during assessments, internal audits and from customer feedback.

**Test methods**

The laboratory applies international method including ISO, AOAC and methods provided by equipment manufacturers. Table 25 below is a summary of tests carried out by the laboratory.

**Table 25: Summary of tests offered by RSB National Quality Testing Laboratory**

|  |  |
| --- | --- |
| CHEMISTRY | MICROBIOLOGY |
| 1. Caffeine in tea and coffee
2. Mycotoxins including OTA, Aflatoxins, Fumonisins B1 & B2, Zearalenone, Patulin, and Deoxynivalenol, M1
3. Pesticide residues
4. PCBs and PAHs
5. Heavy metals
6. Sugars
7. Moisture content
8. Total ash
9. Nitrogen and crude protein content
10. Crude fat
11. Crude fiber content
12. Refractive index
13. Other tests included in the annex
 | 1. *Total coliforms*
2. *Eschelichia Coli*
3. *Salmonella*
4. *Pseudomonas aeruginosa*
5. *Intestinal enterococci/ Enterococcus faecalis*
6. *Spores of Sulfite reducing anaerobes*
7. *Clostridium perfringens*
8. *Total Viable Counts*
9. *Staphylococcus aureus*
10. *Enterobacteriaceae*
11. *Vibrio parahaemolyticus*
12. *Vibrio cholera in food,*
13. *Sulfite reducing anaerobes*
14. *Shigella spp*
15. *Campylobacter spp*
16. *Listeria Monocytogenes*
17. *Bacillus cereus Mesophilic lactic acid bacteria*
18. *TVC, Yeast and Moulds*
 |

* SOPs for the unaccredited methods are in place and method validation is ongoing.
* Validation data is available including the evaluation of measurement uncertainty for the accredited methods. The accreditation schedule is available on the link <https://www.rva.nl/en/search?utf8=%E2%9C%93&q=L638&commit=find+organisation&type=institutions>

**Standard Operating Procedures**

The National Quality Testing Laboratory has implemented the requirements of ISO 17025: 2005 documentation including SOPs for management and technical requirements are in place.

**Quality Assurance**

The laboratory implements quality control procedures, both internal and external. Internal procedures include use of quality control materials and reference standards. External procedures include participation in PTs, FAPAS schemes for Aflatoxin M1 in powdered milk, drinking water quality and safety parameters, Infant formula nutrients and wine quality. The laboratory has participated in the APTECA/FAO-Texas PT scheme from 2016 to date. It also participates in the EAC ILC schemes.

**Gaps identified in the Rwanda National Quality Testing Laboratories**

Table 26 below is a summary of the gaps identified in **National Quality Testing Laboratories**

 **Table 26: Gaps identified in National Quality Testing Laboratories**

|  |  |
| --- | --- |
| **QMS component** | **Gaps** |
| Facilities and environmental conditions | - |
| Human Resources including ongoing training | Personnel exposure and continuous training through attachment in more advanced laboratories |
| Equipment | Service delivery (turnaround time and cost) for equipment repair and maintenance |
| Management | - |
| Test methods | Allergen and residues of veterinary drugs testing is not in the scope. |
| Standard Operating Procedures | - |
| Quality Assurance | Participation in PT is inadequate for chemical testing |
| Scope of accreditation | The scope of chemical methods accreditation is limited and does not include organic contaminants. |
| Others | * Funding for PTs and ILC participation
* Funds for accreditation.
 |

**Conclusions**

* The laboratory meets the minimum requirements for approval under the FSMA. However, there is need to validate the chemical contaminants methods currently in use, expand the scope of testing and accreditation.
* The facilities and environment can accommodate more test work. The ISO 17025:2005 clause 5.3 and ISO 17025:2017 clause 6.3 requirements for facilities and environment have been addressed.
* The academic qualifications of the personnel are relevant to the work areas in the laboratory. However more training through exposure in more advanced laboratories and regional training will enhance personnel skills. The ISO 17025:2005 clause 5.2 and ISO 17025:2017 clause 6.2 requirements for personnel have been addressed
* The currently available equipment is adequate but an extra post column delivertization unit for the HPLC is required. More tests can be accommodated including allergen testing. The ISO 17025:2005 clause 5.5 and ISO 17025:2017 clause 6.4 requirements for equipment have been addressed
* The management system is effective. However, lack of autonomy contributes to delays in carrying out processes including procurement of laboratory supplies and services. The ISO 17025:2005 clause 4 and ISO 17025:2017 clause 8.2 requirements for management have been addressed except for document control.
* The test methods coverage is adequate for conformity assessment, but the scope of accreditation is narrow as it is limited to microbiological parameters and food composition. The ISO 17025:2005 clause 5.4 and ISO 17025:2017 clause 7.2 requirements for test methods have been addressed.
* Participation in PT is not adequate. It does not include chemical contaminants schemes except for aflatoxins. The requirements of ISO 17025:2005 clause 5.9 and isi17025:2017 clause 7.7 for quality assurance are addressed.

**Recommendations**

* Introduce chemical testing methods to include allergens
* Validate the methods currently in use and those to be introduced.
* Continuous training including attachment in laboratories accredited for chemical contaminants tests.
* Training in transitioning from ISO 17025:2005 to the 2017 version.
* Training in equipment troubleshooting and maintenance
* Training in GLP
* Subscription to more PT schemes for food contaminants, i.e. pesticide residues, PCBs and PAHs, heavy metals and other mycotoxins
* Expand the scope of accreditation

## **UGANDA**

**Agricultural exports from Uganda**

In 2018, Uganda exported mostly agricultural products which contributed about 80 per cent of total exports. Coffee was the most important at 22 percent of total exports, followed by tea, and fish coming at number six.In 2017 **t**he main food products from Uganda included coffee which was leading, fish and products, maize tea and cocoa beans, other livestock/dairy, Sesame and beans.

 The Uganda National AGOA strategy 2018-2025 identified products where Uganda has a competitive advantage, namely: casein (a milk nutrient), Arabica coffee, fish fillets, cut flowers (sweetheart roses), home décor and fashion accessories, specialty foods (vanilla, dried fruits), Shea butter. The U.S. imported agricultural products from Uganda totalling to $60 million in 2017. Leading imports categories included: coffee, unroasted ($33 million), spices ($19 million), other dairy products ($6 million), nursery products ($993 thousand), and other vegetable oils ($126 thousand).

Thus, compliance with the FSMA requirements for laboratories which support HACCP programs and conformity assessment of export agricultural products will enhance market access and foreign exchange earnings. Two public laboratories were identified as having potential to support FBOs. They are the Chemistry and Microbiology laboratories under the Uganda National Bureau of Standards (UNBS) and the Directorate of Government Analytical Laboratory (DGAL).

**Assessment findings**

**Uganda National Bureau of Standards-** **Chemistry and Microbiology laboratories**

**Laboratory overview**

The Chemistry and Microbiology laboratories are part of the Uganda National Bureau of Standards which is a government agency under the [Ministry of Trade, Industry and Cooperatives](https://www.google.com/search?q=Ministry+of+Trade,+Industry+and+Cooperatives&stick=H4sIAAAAAAAAAOPgE-LWT9c3NDIqz8gwrFLi0s_VN8jJMUq2MNPSyii30k_Oz8lJTS7JzM_Tzy9KT8zLrEoEcYqtChKLUvNKFBLTU_OSKxex6vhm5mUWlxRVKuSnKYQUJaak6ih45qWUgoUS81IUnPPzC1KLgJrLUosBShBn-3YAAAA&sa=X&ved=2ahUKEwjfz9v9j9nhAhXK6eAKHYeMA3YQmxMoATAYegQIChAO). UNBS is a national reference institution, a competent authority and a regulator. The chemistry and microbiology laboratories do not have satellite sites. Although the statistics were not available, most of the testing services are offered to local traders and exporters. Both laboratories have implemented a quality management system and are accredited by SANAS. They are funded by the central government. According to the management, the laboratory activities will be relocated to a new site before the end of 2019.

A ground verification mission organised by the INTERAFRICAN Bureau (AU-IBAR) for selection of African Food safety Laboratories Centres of Excellence was carried out in the chemistry laboratory form 10th -11th Dec. 2018. This was after the laboratory was shortlisted as a candidate for a centre of excellence. The final decision on the selection had not been communicated by the time of the assessment.

**Facilities and Environment**

* The space in the current facility is limited leading to congestion in the working and sample storage/archiving areas. Water and power supplies are stable.
* Environmental conditions likely to influence the validity of test results have been identified, including humidity and temperature. Environmental conditions are monitored, controlled and recorded in accordance with the relevant specifications, methods and procedures. The practice is extended to areas where the conditions can influence the validity of results including storage areas for reagents, reference materials and samples, samples, sample preparation and equipment areas.
* Access to the laboratory is controlled through security checks and areas with incompatible activities are separated.

**Human Resource**

* The minimum competence requirements set for personnel to carry out microbiological tests include a first degree in food science or a related field, training in the test methods, laboratory equipment, culture media handling and preparation, sample handling and knowledge of aseptic techniques. Minimum requirement for staff in the chemistry department include first degree holders in Chemistry or any related fields, training in the test methods, method validation and measurement uncertainty, equipment handling, QMS based on ISO 17025 and assurance of Quality of results. All the personnel meet the minimum requirements
* Records for competence evaluation are in place including criteria to perform specific tests, training, supervision, authorization and competence monitoring.
* A procedure for training needs assessment is in place. Training is conducted when if needs arise during appraisals, when new staff is engaged, during installation of new staff, on introduction of new equipment, on introduction or revision of methods, when responsibilities change. Retraining is also carried out. Currently there are no ongoing training programs as funds have not been released.

**Equipment**

The laboratory is well equipped to cover the required scope for chemical and microbiological contaminants, food composition and food additives. Table 27 below is a summary of the equipment and their status**.**

**Table 27: Equipment status in the Uganda UNBS laboratory**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Equipment Name** | **Purpose for which it is used** | **Condition (e.g. Working, not working but serviceable or unserviceable)** |
| 1 | ICP-OES | Heavy metal analysis; Pb, Cu, Hg, Fe, Zn, Cd, Cr, Ni, As, etc. | Working |
| 2 | HPLC (2) | Analysis of antibiotics, Preservatives, HMF, Caffeine, Aflatoxins, Hydroquinone etc. | Working |
| 3 | GCMS | Analysis of Pesticides and other organic contaminants | Working |
| 4 | GC with ECD, TSD and FID detectors | Analysis of Pesticides, PCBs, Methanol, etc | Working |
| 5 | AAS | Analysis of Heavy metals, Pb, Cu, Zn, Cd, Cr, Ni, Fe, etc. | Working |
| 6 | UV-VIS- Spectrophotometer | Analysis of Vitamin A, Sulfur, Nitrates, Phosphates, Nitrites,  | Working |
| 7 | Lactoscan milk analyser |  | Working |
| 8 | UV-DERIVERTISER photochemical reactor | Aflatoxin  | Working |
| 9 |  (LCMS/MS) | Antibiotics, aflatoxins, Pesticides and other contaminants in drugs | Working |
| 10 | Protein Analyzer  | Protein Content | Working |
| 11 | Vortex | Sample preparations | Working |
| 12 | Muffle furnace (3) | Ash Content | Working |
| 13 | Drying Oven (3) | Drying and Moisture content | Working |
| 14 | Refractometer | Refractive Index, Moisture and Brix | Working |
| 15 | Homogenizer | Sample preparations | Working |
| 16 | Water bath | Sample preparations | Working |
| 17 | pH/mV Meter | pH determinations | Working |
| 18 | Conductivity meter | Conductivity determinations | Working |
| 19 | pH Meter | Sample preparations | Working |
| 20 | pH/mV Meter | Sample preparations | Working |
| 21 | Heating mantle | Sample preparations | Working |
| 22 | Centrifuge, for milk | Sample preparations | Working |
| 23 | Heating mantle | Sample preparations | Working |
| 24 | Refrigerator | Fresh sample storage and Standards Storage | Working |
| 25 | **Balance** | Weighing | Working |
| 26 | Digital burette | Titrations and determination of Ca, Chlorides, Hardness, Mg, etc. | Working |
| 27 | **Conductivity meter** | Conductivity determinations | Working |
| 28 | **Turbidity meter** | Turbidity determinations |  |
| 29 | TLC Tank | Hydroquinone analysis | Working |
| 30 | i-CHECH FLUOROi-CHECK FLUORO i-CHECK IRONi-CHECK IRON-i-CHECH IODINEi-CHECK CHROMA | For determination of Vitamin A, Iron, Iodine in fortified foods | Working |
| 30 | Microplate reader and kits | Aflatoxin Analysis | Working |
| **MICROBIOLOGY LABORATORY** |
|  | Refrigerator |  |  |
| 1 | LG fridge | Fresh sample storage | Working |
| 2 | Kirch fridge (2) | Culture media storage | Working |
| 3 | LG fridge | Control cultures storage | Working |
| 4 | Leader oven | Sterilisation of Laboratory apparatus | Working |
| 5 | Panasonic autoclaves (2) | Sterilisation of culture media and decontamination of apparatus | Working |
| 6 | Memmert Incubator | *Salmonella* at 350C | Working |
| 7 | Grant water bath | *Salmonella* and *Vibrio cholera* at 420C | Working |
| 8 | Memmert incubator | Yeast and moulds at 250C | Working |
| 9 | WTB Binder incubator | Yeast and moulds at 250C | Working |
| 10 | Esco Incubator | Total plate count at 300C | Working |
| 11 | Esco Incubator | Escherichia coli at 440C | Working |
| 12 | Gallenkamp incubator  | (Total coliforms, *Pseudomonas aeruginosa*, *Enterococcus faecalis*, *Staphylococcus aureus*, *Enterobacteriacea*, Total plate count –Water, *Listeria monocytogenes.*) at 370C | Working |
| 13 | Esco biosafety cabinets (2) | Create sterile environment for analysis of samples | Working |
| 14 | Nuaire biosafety cabinet | Create sterile environment for analysis of samples | Working |
| 15 | Sanyo ultra- low freezer | Storage of control cultures at -700C for up to 5 years | Working |

* Equipment inventories and specific records are maintained by the specific laboratory units. The laboratory does not use equipment located outside the facility
* Procedures for handling, transport, storage, use and planned maintenance for each equipment are in place.
* Calibration programs for all the measurement equipment are in place.

**Management**

* The laboratory is accredited by SANAS and therefore operates under a quality management system. It has developed a quality manual, factoring in the establishment, documentation and maintenance of policies and objectives for the fulfilment of the requirements of ISO 17025 standard. Policies and objectives have been acknowledged at all levels of the laboratory organization.
* The objectives have addressed competence, impartiality and consistent operation of the laboratory
* The laboratory management have evidence of commitment to the development and implementation of the management system and to continually improve it.
* Access to the relevant management documentation by staff is controlled in relation to their responsibilities through document registers and computer access passwords. Any additions or removal of documents is only carried out by the Quality management officer the only personnel with rights to do so.
* A risk register has been developed as required in the ISO 17025:2017 standard. Procedures for identifying opportunities for improvement are in place

**Test methods**

The laboratory applies international methods including AOAC, Codex Alimentarius and ISO. Others include American Public Health Association (APHA), American Water Works Association (AWWA), American Spice Trade Association (ASTA) and ASTM. Table 28 below is a summary of tests carried out in the laboratory

**Table 28: summary of tests in the UNBS laboratory**

|  |  |
| --- | --- |
| CHEMISTRY | MICROBIOLOGY |
| **Food composition**1. Caffeine
2. Hydroxymethylfurfural (HMF) in honey
3. Sodium benzoate
4. Moisture content
5. Protein content
6. Ash content
7. Moisture content
8. Crude fibre
9. Crude fat
10. Calcium
11. Potassium
12. Sodium
13. Peroxide value in fats and oils
14. Vitamins

**Food contaminants**1. Heavy metals
2. Antibiotics
3. Aflatoxins
4. Pesticide residues
 | 1. Total plate count
2. Total coliforms
3. Total coliforms
4. *Escherichia coli*
5. *Staphylococcus aureus*
6. *Salmonella*
7. *Vibrio cholerae*
8. *Yeast and moulds*
9. *Enterobacteriacea*
10. *Listeria monocytogenes*
11. *Pseudomonas aeruginosa*
12. *Enterococcus faecalis*
 |

* The methods are validated, and evaluation of measurement uncertainty is included in the validation.
* The laboratories subcontracts testing to other laboratories, Chemiphar U Ltd Accredited to ISO/IEC 17025: 2005 other referral labs include; Directorate of Government Analytical Lab and Uganda Industrial Research Institute. For evaluation of these laboratories, there is Uganda National Bureau of Standards Laboratory Recognition Scheme based on ISO/17025 Standard. The current accreditation scope is available, <https://www.sanas.co.za/schedules/testing/T0200-01-2019.pdf>

**Standard Operating Procedures**

The laboratory has operated a QMS since 2001. The SOPs for management and technical requirements are in place.

**Quality Assurance**

Quality assurance programs, internal and external are in place. Internal practices include replicate testing, use of CRMs, and recovery tests. Table 29 below is a summary of the PT and ILC schemes subscribed to by the laboratory

**Table 29: Summary of PT /ILC schemes participation by UNBS**

|  |  |  |  |
| --- | --- | --- | --- |
| **MATRIX** | **PARAMETER** | **SCHEDULE****ONCE PER YEAR** | **PROVIDER** |
| Water | Lead, Copper, Cadmium, Nickel, Mercury, Arsenic, Zinc, Chromium, Aluminum, calcium, Sulphate, chloride, potassium, calcium, sodium, pH, conductivity, total dissolved solids | 2014 to 2018 | NAMWATER (PT) |
| Milled Cereals (wheat flour, maize flour;  | Moisture, Crude protein, Crude fibre, Total ash, Acidity of extracted fat, Moisture, Ash, Copper, Iron, Zinc, Crude fat,  | 2014 to 2018 | KEBS (ILC) |
| Milled cereals | Aflatoxins (G1, G2, B1, B2)Total Aflatoxins | 2014 to 2018 | BIPEA FRANCE (PT) |
| Coffee  | Ochratoxin | 2014 to 2018 | BIPEA FRANCE (PT) |
| Grains | Aflatoxins (G1, G2, B1, B2)Total Aflatoxins | 2014 to 2018 | BIPEA FRANCE (PT) |
| Alcohol  | Ethanol, methanol, higher alcohols | 2014 to 2018 | NMISA (PT) |
| Salt | Moisture, Sodium chloride, insoluble matter, sulphates, Calcium, magnesium | 2014 to 2018 | TBS (ILC) |
| Milled cereals | Lead, copper, cadmium, Iron, Zinc, mercury | 2014 to 2018 | BIPEA FRANCE (PT) |
| Fruits and vegetables | Lead, copper, cadmium, Iron, Zinc | 2014 to 2018 | BIPEA FRANCE |
| Honey | Moisture, sucrose, glucose, HMF, PH, electrical Conductivity, Diastase acidity, fructose, glucose, saccharose, maltose. | 2014 to 2018 | BIPEA FRANCE (PT) |
| Honey | Moisture, Hydroxy methyl furfural (HMF), Acidity, Water insoluble matter, Diastase activity, Ash content, Lead, Zinc, Relative density | 2014 to 2018 | TBS (ILC) |
| Sugar | Colour, Moisture, conductivity, Lead, Copper, cadmium | 2014 to 2018 | RBS (ILC) |
| Edible oils | moisture, iodine value, peroxide value, refractive index, Copper , Nickel, Iron | 2014 to 2018 | UNBS (ILC) |
| Edible oils | moisture, iodine value, peroxide value, refractive index, Copper, Nickel, Iron | 2018 to date | DUCARES BV Netherlands(PT) |
| Fertilizers | Ammoniacal Nitrogen, Water soluble phosphate, Total phosphorus, Moisture, Potassium | 2014 to 2018 | KEBS (ILC) |
| Black tea | Water extract, Total ash, Water insoluble ash, Alkalinity of water-soluble ash, Acid insoluble ash, Crude fiber | 2014 to 2018 | BBS (ILC) |
| Meat and meat products | Antibiotics residues | 2014 to 2018 | EUROFINS(PT) |

Other PT schemes participation include:

* APTECA/FAO-Texas A&M (Aflatoxins in maize)
* LGC Standards UK - Quality in Food scheme, Quality in water scheme, Sugar scheme, Meat and Fish scheme, Cosmetics scheme.
* SADCMET PT – Drinking water PT
* EAC PT organized by KEBS (2018 only) Quality – Meat and Fish scheme, Skimmed milk PT, Black tea scheme

**Gaps identified in the UNBS laboratories**

Table 30 below is a summary of the gaps identified in the UNBS laboratories

 **Table 30: Gaps identified in the UNBS National Quality Testing Laboratories**

|  |  |
| --- | --- |
| **QMS component** | **Gaps** |
| Facilities and environmental conditions | Limited working and sample storage/archiving space in the current facility |
| Human Resources including ongoing training | Personnel exposure and continuous training through attachment in more advanced laboratories |
| Equipment | Major equipment, LCMSMS, needs duplication to handle the high sample volumes |
| Management | - |
| Test methods | Allergen testing is not included in the scope. |
| Standard Operating Procedures | - |
| Quality Assurance | - |
| Scope of accreditation | Limited, does not include pesticide residues, mycotoxins other than aflatoxins, other organic contaminants and mercury |

**Conclusions**

* The UNBS laboratory meets the minimum requirements for approval under the FSMA.
* Although there is congestion in the current facility, The ISO 17025:2005 clause 5.3 and ISO 17025:2017 clause 6.3 requirements for facilities and environment have been addressed.
* There is a training need for allergen testing, continuous training through attachments in more advance laboratories and through regionally organised forums. The ISO 17025:2005 clause 5.2 and ISO 17025:2017 clause 6.2 requirements for personnel have been addressed
* Additional equipment, GCMSMS, is required. The current laboratory space may not accommodate additional equipment and purchase may be considered when the laboratory relocates to the new site. The ISO 17025:2005 clause 5.5 and ISO 17025:2017 clause 6.4 requirements for equipment have been addressed
* The management system is adequate for the current scope of work. The ISO 17025:2005 clause 4 and ISO 17025:2017 clause 8.2 requirements for management have been addressed
* There is capacity to expand the scope of testing to include a wider range of contaminants, pesticide residues, mycotoxins other than aflatoxins, other organic contaminants and mercury. The ISO 17025:2005 clause 5.4 and ISO 17025:2017 clause 7.2 requirements for test methods have been addressed.
* Documentation of the quality system meets the requirements of ISO17025
* Participation in PT satisfactory but more schemes are required, e.g. pesticides and mycotoxins other than aflatoxins. The requirements of ISO 17025:2005 clause 5.9 and isi17025:2017 clause 7.7 for quality assurance are addressed.

**Recommendations**

* Plan for personnel training to facilitate expansion of testing and accreditation scope
* Expand the scope of testing to include allergen testing among other parameters, when the laboratory relocates to the new facility.
* Planning for acquisition of additional equipment, prioritise GCMSMS and an extra LCMSMS
* Expedite the re-accreditation process after relocation to the new site

**Directorate of Government Analytical Laboratory**

**Laboratory overview**

The Directorate of Government Analytical Laboratory is under the Ministry of Internal Affairs. It is a public regal entity designated by the state to carry out official controls. It plays the role of a reference laboratory and has satellites in Mbale, Mbarara, Moroto and Gulu. Customers include exporters, local traders, farmers, consumers, environmentalists, researchers and subcontracting agencies e.g. UNBS. The highest volume of samples is from local traders, environmentalists and exporters. Funding is from the Central government. The laboratory has not implemented a QMS.

**Facilities and Environment**

* The laboratory has stable water and power supply. A standby power generator is in place.
* Dust and temperature have been identified as environmental conditions that can influence the validity of test results and controls are in place.
* Monitoring, control and recording of environmental conditions in accordance with relevant specifications, methods, and procedures or where they influence the validity of results has not been implemented in some areas including reagent storage, sample preparation and equipment areas.
* Access to the laboratory is controlled through the installation of a biometric electronic system. Areas with incompatible laboratory activities are separated.

**Human Resource**

* The personnel engaged in testing have the required academic qualifications. However, they lack training key areas required for the implementation and maintenance of a QMS e.g., method validation including estimation of measurement uncertainty, internal auditing, data analysis and interpretation.
* Personnel records are not in place and there are no competence criteria set for the different tests, hence no competence evaluation of personnel.
* There is no documented procedure for determining training needs.

**Equipment**

The Directorate of Government Analytical Laboratoryhas the basic equipment to test chemical and microbiological contaminants as shown in table 31 below

**Table 31: Directorate of Government Analytical Laboratory eequipment’s list, use and condition**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Equipment Name** | **Purpose for which it is used** | **Condition (e.g. Working, not working but serviceable or unserviceable)** |
| 1 | GC/ECD  | OCPs Residues analysis | Working but very old acquired in 2000 (19 years) |
| 2 | GC/FID  | Pesticide Formulations, alcoholic beverage content | Not working, 19 years old |
| 3 | AAS  | Metallic elemental analysis | Working acquired 2 years ago |
| 4 | HPLC/UV  | Drugs, Food supplements, contaminants and herbicides among others | Working and recently acquired |
| 5 | LCMS/MS  | Mycotoxins, pesticide Residues and drugs | Working, acquired less than 2 years ago  |
| 6 | GCMS/MS  | Pesticide residues, food contaminant and volatile toxic organic compounds | Working, **but being shared between analysis of toxicological levels and residue levels.** |
| 9 | UV spectrometer X3 | Drugs and vitamins | Working |
| 10 | DR (Direct Reading Spectrometer) | Elemental and nutrient analysis in water | Working |
| 11 | XRF | Elemental analysis in soil and other materials | Working |
| 12 | Genetic Analyzer X 2 | DNA profiling | Working |
| 13 | PCR X 2 | Gene amplification and quantitation | Working |
| 14 | Water purification system | Water Purification  | Working |
| 15 | Microwave digester | Digestion of samples | Not working, BUT repairable |
| 16 | FT IR | Drugs and other material  | New |

* The only equipment record available is an inventory. Some of the equipment is shared between departments and there is no written procedure for this arrangement.
* A procedure for handling, transport, storage, use and planned maintenance for each equipment is not in place.
* Although equipment which require calibration have been identified, calibration programs are not in place.

**Management**

* Although the laboratory has not implemented a QMS, a draft quality manual is in place factoring in the establishment, documentation and maintenance of policies and objectives for the fulfilment of the requirements of ISO 17025 standard. Staff has been sensitized on the same.
* The objectives have addressed competence, impartiality and consistent operation of the laboratory.
* The laboratory management have evidence of commitment to the development and implementation of the management system and to continually improve it and is aligned to the Quality objectives.
* The practices in document control are not aligned to the requirements of ISO 17025
* There is no procedure for identifying opportunities for improvement.
* A risk register has not been established.

**Test methods**

The test methods applied are international. They include EPA, APHA, HACH, Codex Alimentarius and AOAC. Table 32 below is a summary of the tests carried out in the laboratory

**Table 32: Summary of test carried out in the DGAL**

|  |  |
| --- | --- |
| CHEMISTRY | MICROBIOLOGY |
| **Food composition**1. Moisture content
2. Protein content
3. Ash content
4. Moisture content
5. Crude fibre

**Food contaminants**1. Heavy metals
2. Antibiotics
3. Pesticide residues
4. Aflatoxins
 | 1. Total plate count
2. Total coliforms
3. *Escherichia coli*
4. *Staphylococcus aureus*
5. *Salmonella*
6. *Vibrio cholerae*
7. *Yeast and moulds*
8. *Enterobacteriacea*
9. *Listeria monocytogenes*
10. *Pseudomonas aeruginosa*
11. *Enterococcus faecalis*
 |

There was no validation data for the test methods and the SOPs were not in place. The scope testing does not include allergens

**Standard Operating Procedures**

Documentation of the laboratory processes and procedures does not meet the requirements of ISO17025 standards.

**Quality Assurance**

Quality assurance procedures are not documented. However, the laboratory participates in PT and ILC schemes summarised in table 33 below

**Table 33: Summary PT/ILC schemes participation by DGCL**

|  |  |  |
| --- | --- | --- |
|  | **PT/ILC** | **PROVIDER** |
| **1** | Food composition | EAC  |
| **2** | Water quality | Namibia Water Corporation  |
| **3** | Chemical Analyses of Portable Water in Africa | **SADMET** |
| **4** | Aflatoxin PT scheme | Texas A & M Agrilife Research |
| **5** | Pesticide Residues PT Scheme | NMISA  |
| **6** | DNA PT Scheme | GEDNAP- |
| **7** | POPs | UNEP  |
| **8** | Drugs and Crime IEC-PT Scheme | United Nations |

**Gaps identified in the DGCL**

The laboratory has not implemented a QMS. Although there is a degree of documentation, there is no roadmap towards implementation and subsequent accreditation. Table 34 is a summary of the identified gaps

**Table 34: Summary of gaps identified in DGCL Uganda**

|  |  |
| --- | --- |
| **QMS component** | **Gaps** |
| Facilities and environmental conditions | QMS requirement have not been addressed |
| Human Resources including ongoing training | Personnel have not been trained in the requirements of ISO 17025 |
| Equipment | An extra GCMSMS is required to avoid sharing between laboratories |
| Management | A draft quality manual is in place.  |
| Test methods | Test methods are not validated.  |
| Standard Operating Procedures | Documentation in the laboratory is inadequate. SOPs for most processes are not in place |
| Quality Assurance | Internal QC procedures are in place. External procedures are not adequate |
| Scope of accreditation | The laboratory is not accredited |

**Conclusions**

* The laboratory does not meet the minimum requirements for FSMA approval.
* The requirements of the ISO17025 standard have not been addressed
* There is adequate space to carry out food contaminants and composition tests and there is room for scope extension.
* There is an urgent need for personnel training in the requirements of ISO17025. Of priority is training in documentation, method validation, estimation of measurement uncertainty, internal auditing data analysis and interpretation**.**
* There is need for the personnel to be attached to accredited laboratories.

 **Recommendations**

* Train personnel in the requirements of ISO 17025:2017
* Continue with the documentation of the laboratory processes beyond the quality manual.
* Prepare validation plans for the existing test method and commence the validation.
* Identify and participate in PT schemes relevant to the tests
* Organise for personnel attachment to accredited laboratories in the region.
* Prepare a roadmap to accreditation and initiate the process

## **ZAMBIA**

The key food exports from Zambia are dominated by Sugar, sugar confectionery and cereals. Other foods exported includes coffee tea, beverages, oil seeds, resins and vegetable extracts, fruits and nuts. In 2017 the U.S. total imported agricultural products from Zambia totalled $2 million. This were mainly coffee, tea, dairy, eggs, and honey products. Regarding exports to US, the exports have been minimal and mostly bulk products such as unpacked honey. There is a potential market for the above products if the price is competitive and the product meets the food safety requirements as set in the FDA FSMA. There is therefore a need to have laboratories which meet the criteria set by the act to allow for recognition by FDA as having the capacity to support HACCP in FBOs exporting to the US. Two laboratories hosted by the Zambia Bureau of Standards (ZABS) and Zambia Agricultural Research Institute (ZARI) were assessed for gaps regarding meeting the requirements of FSMA.

**Assessment findings**

**Zambia Bureau of Standards Testing Laboratories**

**Laboratory overview**

The laboratory is a legal public entity and has a regulatory role. It is a national reference laboratory and has a role in official controls for foods consumed locally. 95% of its customers are local traders while 1.7% are exporters. Funding is from the government and grants.

It has a QMS in place and is accredited for chemical testing by the South African Development Community Accreditation Service (SADCAS).

**Facilities and Environment**

* The laboratory has stable power and water supplies.
* The available space is adequate for the current scope of testing.
* Environmental conditions likely to influence the validity of test results have been identified
* Requirements for facilities and environmental conditions necessary for the performance of the laboratory activities have been documented
* Environmental conditions are monitored, controlled, and recorded in accordance with relevant specifications, methods, and procedures where they influence the validity of results
* Access to the laboratory is controlled and areas with incompatible laboratory activities are separated,

**Human Resource**

* The number of personnel in the chemistry and microbiology laboratories is adequate for the current volume of work. They have the required academic qualifications and competences.
* Personnel records are in place including competence evaluation for the performance of specific tests, selection criteria to perform specific tests, training, supervision, authorization and competence monitoring. Supervisors identify training needs for personnel.
* There is no written procedure for identifying training needs.

**Equipment**

The ZABS microbiology and chemistry laboratories are well equipped for food composition and contaminants testing. Table 35 is a summary of equipment available in the laboratories.

**Table 35: Equipment available in ZABS chemistry and microbiology laboratories**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Equipment Name** | **Purpose for which it is used** | **Condition (e.g. Working, not working but serviceable or unserviceable)** |
| 1 | AAS | Elemental Analysis in Food and None food samples | **Working** |
| 2 | OES | Elementa Analysis in Food and Non-food samples | **Working** |
| 3 | HPLC | Pesticide Residues, Vitamin A | **Working** |
| 4 | GC | Hydrocarbon, Alcohol | **not working but serviceable** |
| 5 | GCMS | Pesticide Residues, Hydrocarbons and Organic Volatiles |  |
| 6 | MPAES |  |  |
| 7 | Vicam Fluorometer | Aflatoxins and Other Mycotoxins | **Working** |
| 8 | Accuscan Gold | Aflatoxins and Other Mycotoxins | **Working** |
| 9 | ICP | Elementa Analysis in Food and None food samples | **Working** |
| 10 | XRF | Elemental Analysis in Environmental samples | **Working** |
| 11 | Carbon Sulphur Analyzer | Carbon and Sulphur Analysis | **Working** |
| 12 | Sulphur Analyzer | Sulphur Analysis | **Working** |
| 13 | Fluorospectrophotometer96 |  | **Working** |
| 14 | Perten DA 7250 | Cereal and Feed Analysis | **Working** |
| 15 | VELP NDA 701 | Nitrogen and Protein Analysis | **not working but serviceable** |
| 16 | Furnaces | Ashing of Samples | **Working** |
| 17 | UV/VIS 1800 | Organic Analysis,Nitrates,Phosphates, Vitamins | **Working** |
| 18 | FOODSCAN | Meat Analysis | **Working** |
| 19 | Incubator | Incubating Samples For microbiological Analysis | **Working** |
| 20 | Colony Counter | Colony Counting | **Working** |
| 21 | Microscope | Microscopic Analysis or viewing of as small as 0.2microns | **Working** |
| 22 | Safety Cabinet | Sample preparation | **Working** |
| 23 | Laminar Flow Bench Type | For sample innoculation | **Working** |

The following requirements are in place:

* Records of the equipment that can influence laboratory activities
* Procedures for handling, transport, storage, use and planned maintenance for each equipment.
* Calibration programs for all the measurement equipment

**Management**

The laboratory has addressed the management requirements of ISO 17025.

**Test methods**

The laboratory applies AOAC and Codex Alimentarius test methods. The testing procedures are documented. Table 36 below is a summary of the tests carried out in the laboratory

**Table 36: Tests carried out in the ZABS chemistry and Microbiology laboratories**

|  |  |
| --- | --- |
| **CHEMISTRY** | **MICROBIOLOGY** |
| **Food composition** 1. Determination of Ca, Cu, Fe, K, Mg, Mn, Na and Zn in Animal Feeds
2. Determination of Moisture and Volatile Matter in animal feed
3. Determination of Moisture Content, volatile matter and total ash in maize meal
4. Determination of Moisture, Protein and Total Ash in wheat flour.
5. Determination of Ca, Cd, Co, Cr, Cu, Fe, K, Mg, Mn, Ni and Zn pH and Nitrates in water
6. Analysis of volatile organic compounds
7. Determination of sugar profiles
8. Total fat determination

**Contaminants**1. Pesticide residues analysis
2. Heavy metals
3. Mycotoxins
 | 1. Total coliforms
2. *Staphylococcus aureus*
3. *Salmonella*
4. Yeast and moulds
5. *Enterobacteriacea*
6. *Faecal coliforms*
7. Aerobic plate count
8. *Eschericha coli*
 |

Validation data for accredited test methods was available. The current accreditation certificate is available on the SADCAS website link <https://www.sadcas.org/zambia-bureau-standards-testing-0>

**Standard Operating Procedures**

Standard operating procedures for the management and technical processes are in place

**Quality Assurance**

* Provide a list of reference materials used in the laboratory, providers, associated service providers and their accreditation status.
* Both internal and external QC procedures are in place for the accredited methods. Reference materials include Accustandard, Restex and Microbiologics. The laboratory participates in the following PTs and ILCs:
	+ APTECA PT
	+ National Metrology Institute of South Africa, (NMISA)
	+ SADCMET,
	+ NLA,
	+ EAC,
	+ FAPAS
	+ Agricultural Laboratory Association of Southern Africa (**AgriLASA**)

**Gaps identified in the ZABS chemistry and microbiology laboratories**

Table 37 below is a summary of the gaps identified in the ZABS laboratories

 **Table 37: Gaps identified in the ZABS laboratories**

|  |  |
| --- | --- |
| **QMS component** | **Gaps** |
| Facilities and environmental conditions | - |
| Human Resources including ongoing training | * Funding for training and retraining personnel is inadequate.
* Exposure to modern testing technology is inadequate
 |
| Equipment | * Equipment maintenance and repair services are expensive and not readily available.
* There is a capacity gap in personnel competence for equipment maintenance and trouble shooting
 |
| Management | - |
| Test methods | * Allergen testing is not included in the scope.
* Mycotoxins other than aflatoxins are not included in the scope of testing.
 |
| Standard Operating Procedures | - |
| Quality Assurance | There is a gap in funding for CRMs and participation in PTs. |
| Scope of accreditation | Limited to food composition and aflatoxin testing. |

**Conclusions**

* The laboratory meets the minimum requirements for recognition under the FSMA. However, the scope accreditation is narrow
* The laboratory space is adequate and can accommodate more tests. The ISO 17025:2005 clause 5.3 and ISO 17025:2017 clause 6.3 requirements for facilities and environment have been addressed
* Although the laboratory does not have a procedure for training needs identification, it was indicated that there is inadequate funding for training and the personnel are not exposed to modern techniques. The ISO 17025:2005 clause 5.2 and ISO 17025:2017 clause 6.2 requirements for personnel have not been addressed
* Personnel competence in equipment maintenance is limited. The ISO 17025:2005 clause 5.5 and ISO 17025:2017 clause 6.4 requirements for equipment have been addressed
* The ISO 17025:2005 clause 4 and ISO 17025:2017 clause 8.2 requirements for management have been addressed.
* The scope of testing is not adequate to address most food tests required trade. The ISO 17025:2005 clause 5.4 and ISO 17025:2017 clause 7.2 requirements for test methods have been addressed.
* Documentation of the quality system meets the requirements of ISO17025.
* Quality assurance procedures are adequate for the current scope of testing. The requirements of ISO 17025:2005 clause 5.9 and isi17025:2017 clause 7.7 for quality assurance are addressed.

**Recommendations**

* Expand testing and accreditation scope to include allergen testing among others
* Explore opportunities for personnel attachment to advanced and accredited laboratories for exposure to modern techniques, and equipment maintenance.
* Include allergen and more contaminants testing in the scope and validate the same for inclusion in the accreditation scope.

**Zambia Agricultural Research Institute Food laboratory**

**Laboratory overview**

The laboratory is based in a national public research organization and is therefore a legal entity. It has satellites in some parts of the country. Although the laboratory is research based, the bulk of the testing was offered to exporters and local traders at 50% and 20% respectively in 2017. Research contributed on 15% of the total workload. Funding is from the government. The laboratory is not accredited and has not implemented a QMS.

**Facilities and Environment**

* The laboratory space is adequate. There is adequate power supply.
* According to the staff, water supply is not adequate.
* There is a cement factory emitting dust in the neighbourhood. The emissions are likely to affect the quality of test results.
* There is partial documentation of the requirements for facilities and environmental conditions necessary for the performance of the laboratory activities.
* Although the staff indicated that they monitor, control and record environmental conditions in accordance with relevant specifications, methods, and procedures or where they influence the validity of results, there was no supporting evidence.
* Accesses to the laboratory is controlled and areas with incompatible laboratory activities are separated.

**Human Resource**

* The laboratory personnel have the basic academic qualifications. They have undergone basic inhouse training but have not undergone competence evaluation.
* There are no personnel records
* Training is conducted when new equipment is procured. There is an ongoing training program on operation of new equipment

**Equipment**

The laboratory has procured modern equipment which is awaiting installation. When the equipment is fully operational, the laboratory will have the capacity to analyse organic contaminants and allergens. Table 38 below is a summary of the equipment available in the laboratory

**Table 38: Equipment available in the ZARI Food Laboratory**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Equipment Name** | **Purpose for which it is used** | **Condition (e.g. Working, not working but serviceable or unserviceable)** |
| 1 | Agilent 1200 HPLC MS  | Aflatoxins, drug residues | LC working, MS needs servicing |
| 2 | Shimadzu HPLC MS | Aflatoxins, drug residues | Yet to be installed |
| 3 | Shimadzu GC MS | Aflatoxins, drug residues | Yet to be installed |
| 4 | Agilent GC MS | Aflatoxins, drug residues | Yet to be installed |
| 5 | Agilent 4210 MPAES | Heavy metals | Not working but serviceable |

* The laboratory has no calibration programs for measurement equipment.
* Equipment procedures have not been documented.

**Management**

* The laboratory has not developed a quality manual and therefore does not have developed policies, and objectives for the fulfilment of ISO 17025.
* The laboratory management has no evidence of commitment to the development and implementation of the management system and to continually improve it
* There is no control of access to the relevant management documentation by staff.

**Test methods**

* The laboratory employs International testing methods and guidelines, AOAC and Codex. The following tests are carried out in food commodities:
	+ Aflatoxins
	+ Pesticide residue
	+ Carotenoids
	+ Heavy metals
	+ Residues of veterinary drugs

The test methods have not been validated

**Standard Operating Procedures**

Standard operating procedures are not in place. However, preparation has commenced.

**Quality Assurance**

The laboratory has not documented its quality assurance procedures. The only QC evidence is participation in the Aflatoxins in Ground Corn provided by the office of the State Chemist of Texas*.*

**Gaps identified in the ZARI laboratory**

Table 39 below is a summary of the gaps identified in the ZABS laboratories

 **Table 39: Gaps identified in the ZARI laboratories**

|  |  |  |
| --- | --- | --- |
|  | **QMS component** | **Gaps** |
| 1 | Facilities and environmental conditions | The buildings are old and need refurbishing to accommodate modern technology. |
| 2 | Human Resources including ongoing training | The human resource is adequate in terms of numbers, but there is lack of formal training in Quality Assurance, Method Validation and general good laboratory practices |
| 3 | Equipment | * Operationalization of the newly acquired equipment
* The current equipment (HPLC) is in working order but requires new separation columns as well as a Post Column Derivatization component.
* No water purification system that would reduce the cost of HPLC analysis
 |
| **4** | Management | The management system does not meet the requirements of ISO17025 standard |
| 5 | Test methods | * Test methods are not validated.
 |
| **6** | Standard Operating Procedures | SOPs are not in place |
| **7** | Quality Assurance | Procedures and practices not in place |
| **8** | Scope of accreditation | The laboratory has no accreditation |

**Conclusions**

* The laboratory has not implemented a QMS and therefore does not meet the minimum requirements of the FSMA
* The activities in the surrounding environment can affect the quality of test results. The ISO 17025:2005 clause 5.3 and ISO 17025:2017 clause 6.3 requirements for facilities and environment have not been addressed.
* Personnel training in equipment operation and maintenance is required for continuous functioning of the instruments. There is minimal exposure of personnel to modern techniques. The ISO 17025:2005 clause 5.2 and ISO 17025:2017 clause 6.2 requirements for personnel have been addressed
* The ISO 17025:2005 clause 5.5 and ISO 17025:2017 clause 6.4 requirements for equipment have not been addressed
* The laboratory can accommodate a wide scope of testing after the installation of the new equipment. The ISO 17025:2005 clause 5.4 and ISO 17025:2017 clause 7.2 requirements for test methods have been addressed.
* The ISO 17025:2005 clause 4 and ISO 17025:2017 clause 8.2 requirements for management have not been addressed.
* The ISO 17025:2005 clause 5.4 and ISO 17025:2017 clause 7.2 requirements for test methods have not been addressed.
* The requirements of ISO 17025:2005 clause 5.9 and ISO 17025:2017 clause 7.7 for quality assurance are not addressed.

**Recommendations**

* The laboratory should consider implementing a QMS
* Train personnel in the requirements of ISO 17025:2017
* Train personnel by attaching them in relevant accredited laboratories.
* Expedite the installation of new equipment
* Validate the test methods currently covered in readiness for accreditation. Plan to introduce more tests including for allergen testing
* Document and implement QC procedures, subscribe to relevant PT schemes.

# **CONCLUSIONS**

* All the laboratories require to implement the 2017 version of the ISO17025 Standard. By 2020. This will ensure the maintenance of eligibility for recognition under the FSMA for the accredited laboratories.
* None of the assessed laboratories has implemented allergen testing.
* There is a gap in the availability of PT and ILC schemes relevant to the scope of tests in the laboratories.
* Equipment maintenance and repair is a challenge to most of the laboratories. In most of the cases, the challenge emanates from the level of involvement of laboratory personnel in procurement and the procurement process. Another factor is the laboratory management system with respect to equipment.
* Out of the 7 countries covered in the laboratory gap assessment, it is only Madagascar which did not have an accredited public food testing laboratory or one which has implemented a QMS, table 41 annex 1 below. Support for Madagascar laboratory will require investing in equipment and personnel training to for it to commence QMS implementation
* Among the 7 countries the three highest ranked exporters of agricultural commodities to the US are Ethiopia, Kenya and Uganda in that order, table 42 annex 1 below. The three countries have well equipped and accredited laboratories which cover the range of tests, except for allergen testing, required for exports to the US.
* In Ethiopia, the ECAE is accredited and offers a wide range of tests. However chemical test methods are not validated and are not in the scope of accreditation. A different laboratory, the **A**gricultural Products Quality Monitoring and Testing Laboratory (APQMTL) was better equipped and mandated for chemical contaminant testing in agricultural produce. The private laboratory included in the assessment has since lost its accreditation. Effective support for Ethiopia would not require heavy investment in equipment and would have to include the ECAE and APQMTL laboratories (they are in the same facility), but there are issues that would have to be addressed at the government level.
* In Kenya, the KEBS and KEPHIS laboratories are accredited. The NPHL has implemented a QMS. The three laboratories work collaboratively in food safety testing. The KEPHIS laboratory is more advanced and specialised in conformity assessment of agricultural commodities including plant health and food safety. Support for Kenya would not require heavy investment in equipment and would have to involve the three laboratories with KEPHIS as the focal point.
* In Uganda, the UNBS laboratory is accredited and offers a wide range of tests on export commodities. Support for the laboratory would initially not require heavy investment in equipment. The relocation to a new site before the end of 2019 gives the laboratory an opportunity to have a modern outlook. As a rule, the laboratory will have to suspend its accreditation during the relocation. Support for the laboratory would have to commence after re-accreditation
* The U.S. total imports of agricultural products from Mauritius, Rwanda and Zambia are relatively low. The countries have accredited laboratories with capacity to support trade within and outside COMESA.
* KEBS and UNBS are providers of ILCs and they have the capacity to expand to address existing gaps in COMESA laboratories

# **RECOMMEDATIONS**

* Select countries to be supported based Agricultural products export volumes to the US and the level of compliance of their laboratories to the minimum FSMA requirements.
* The countries selected for support to engage with exporters/FBOs and the relevant trade departments in their countries to come up with detailed testing needs to enable prioritization of scope expansion including the incorporation of the tests in the accreditation scope.
* Facilitate introduction of selected allergen testing in the assessed laboratories with capacity for the analysis. This can be coordinated electronically with a practical training in one of the laboratories.
* Together with the development partner, identify a laboratory in the US where a practical training of trainers in allergen testing can be conducted.
* Organise a forum for laboratories to discuss, among others, relevant PT schemes including those for allergens, equipment procurement and maintenance.
* Support laboratories currently providing ILCs to be accredited to and expand to address the PT gaps in the COMESA laboratories.

# **ANNEXES**

**Annex 1: Summary tables**

**Table 40: Summary of counties, laboratories, test grouping and accreditation status**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **ETHIOPIA** | **KENYA** | **MADAGASCAR** | **MAURITIUS** | **RWANDA** | **UGANDA** | **ZAMBIA** |
|  | **ECAE** | **BLESS** | **KEBS** | **KEPHIS** | **NPHL** | **LHAE** | **FTL** | **NQTL** | **DGCL** | **UNBS** | **ZABS** | **ZARI** |
| **QMS Implementation** | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | X | 🗸 | 🗸 | X | 🗸 | 🗸 | X |
| **Accreditation** | 🗸 | X | 🗸 | 🗸 | X | X | 🗸 | 🗸 | X | 🗸 | 🗸 | X |
| **Chemical contaminants testing** | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 |
| **Microbiological contaminants testing** | 🗸 | 🗸 | 🗸 | 🗸 | X | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | X |
| **Food composition testing** | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 | 🗸 |
| **Allergen testing** | X | X | X | X | X | X | X | X | X | X | X | X |

**Table 41: Summary of agricultural import value by the US for the 7 countries**

|  |  |  |
| --- | --- | --- |
| **COUNTRY** | **EXPORTS TO THE US - GLOBAL RANKING-** | **U.S. total imports of agricultural products from country (Million USD)** |
| **Ethiopia** | 102 | 174 |
| **Kenya** | 86 | 165 |
| **Madagascar** | - | - |
| **Mauritius** | 104 | 12 |
| **Rwanda** | 147 | 22 |
| **Uganda** | 130 | 60 |
| **Zambia** | 135 | 2 |

**NB: The global ranking considered all categories of exports**

**Annex 2: persons met**

|  |
| --- |
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